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Morin et al.

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(54) **COLLAPSIBLE LEAFLETS FOR PROSTHETIC HEART VALVES**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 96 days.

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(65) **Prior Publication Data**

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Related U.S. Application Data

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(51) **Int. Cl.**
A61F 2/24 (2006.01)

(52) **U.S. Cl.**
CPC ***A61F 2/2418*** (2013.01); *A61F 2250/001* (2013.01)

(58) **Field of Classification Search**
CPC A61F 2/24; A61F 2/2418; A61F 2/2475; A61F 2/2409; A61F 2/246; A61F 2/2427
See application file for complete search history.

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Primary Examiner — Seema Mathew
(74) *Attorney, Agent, or Firm* — Sleman & Lund LLP

(57) **ABSTRACT**

A prosthetic heart valve may include an expandable stent, a cuff attached to an annulus section of the stent, and a plurality of leaflets disposed within an interior region of the stent and attached to at least one of the cuff or the stent. The stent may have a plurality of cells connected to one another in a plurality of annular rows around the stent. The leaflets together may have a coapted position occluding the interior region of the stent and an open position in which the interior region is not occluded. Each leaflet may include a primary leaflet material, as well as features that reinforce specific regions of the leaflet.

15 Claims, 7 Drawing Sheets

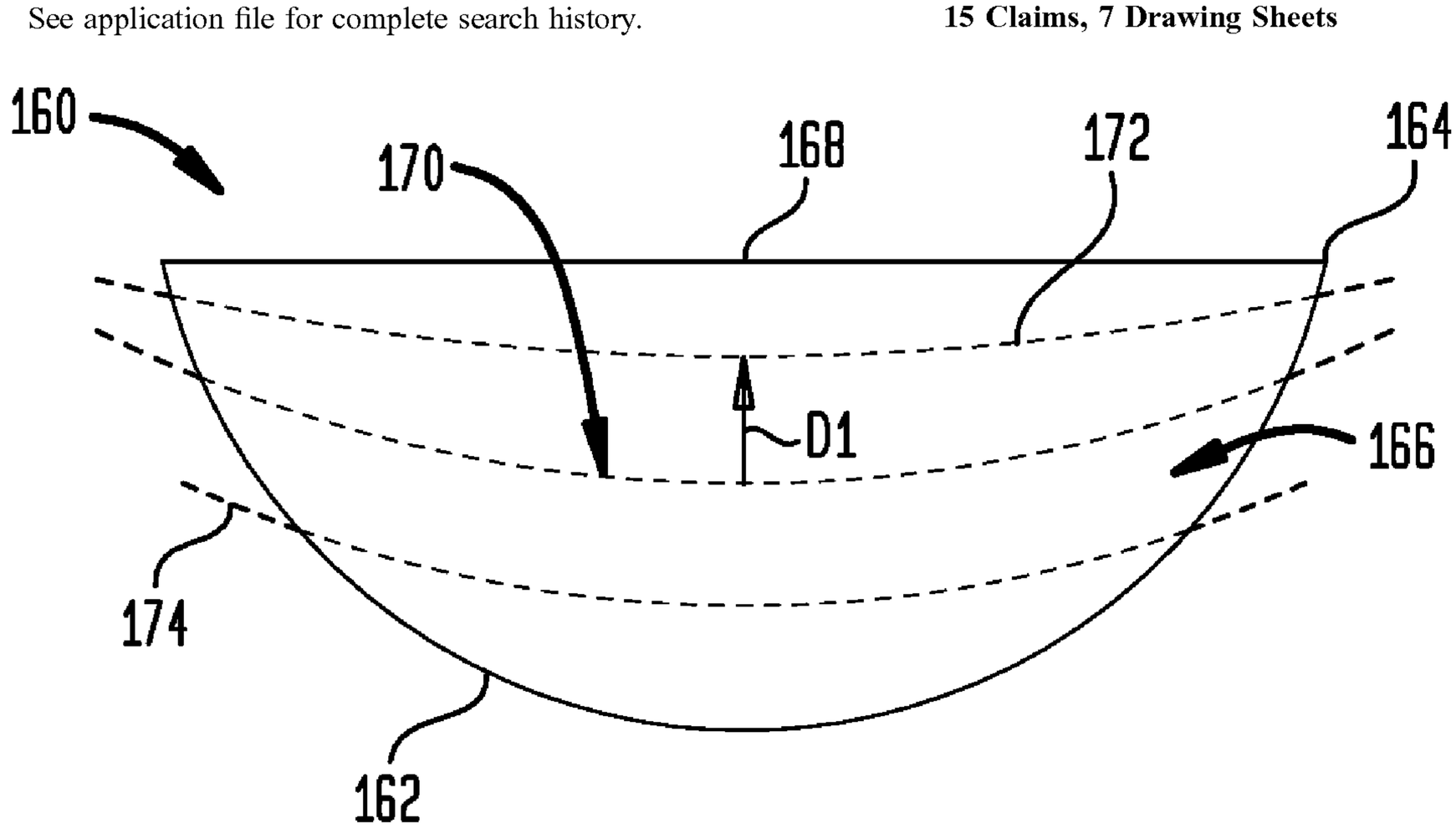

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FIG. 1
(PRIOR ART)

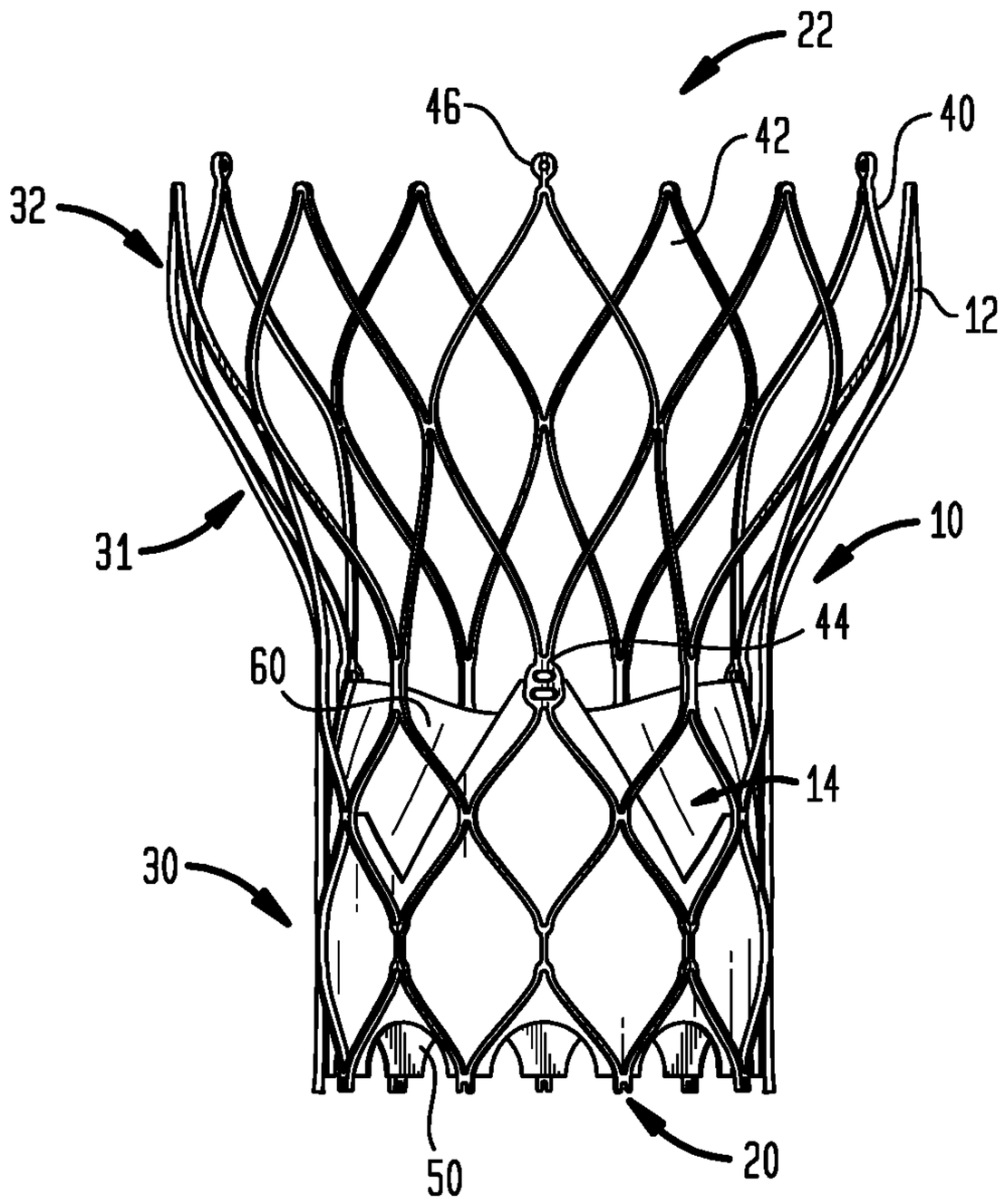


FIG. 2A

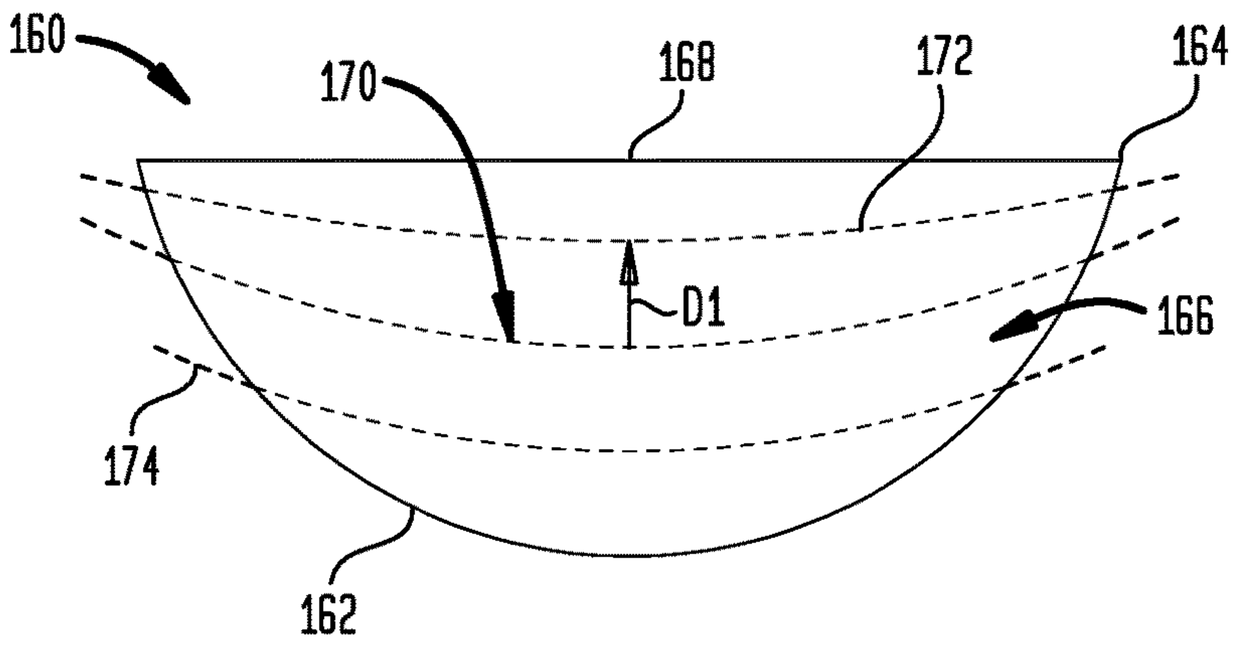


FIG. 2B

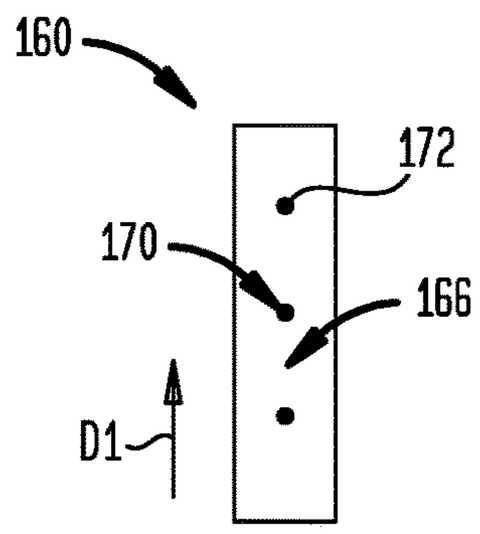


FIG. 2C

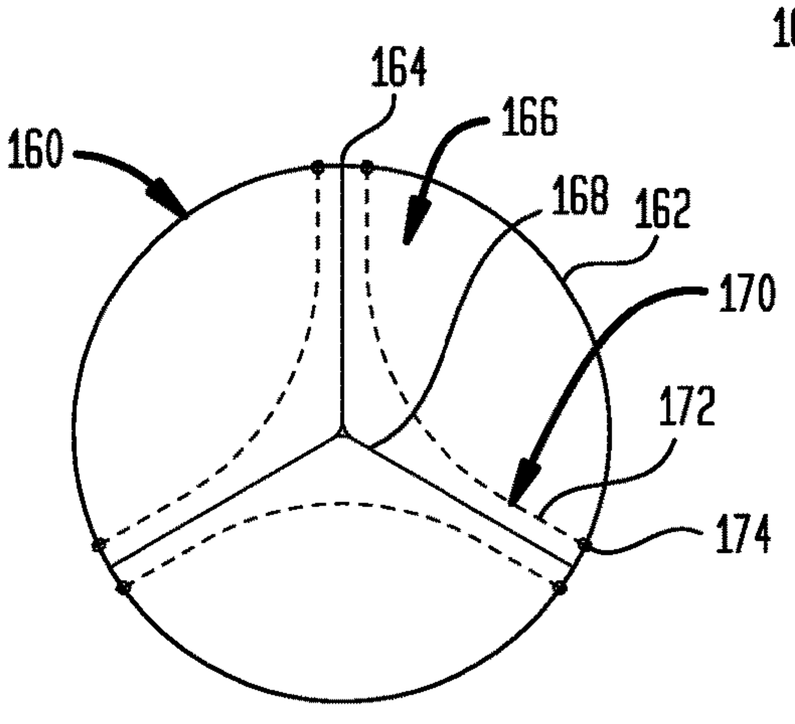


FIG. 2D

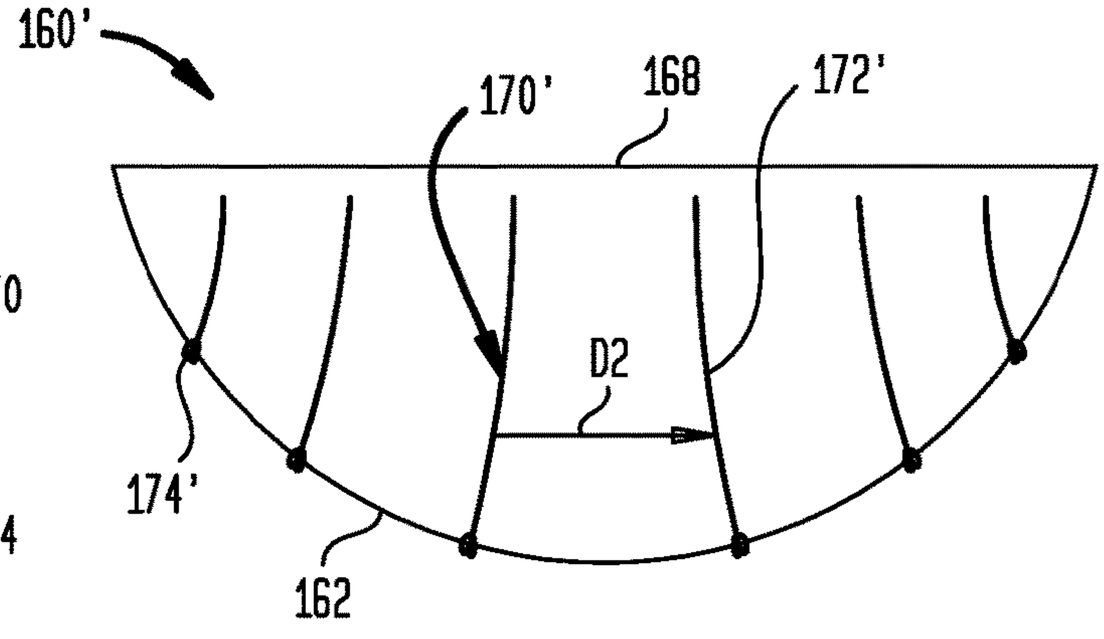


FIG. 2E

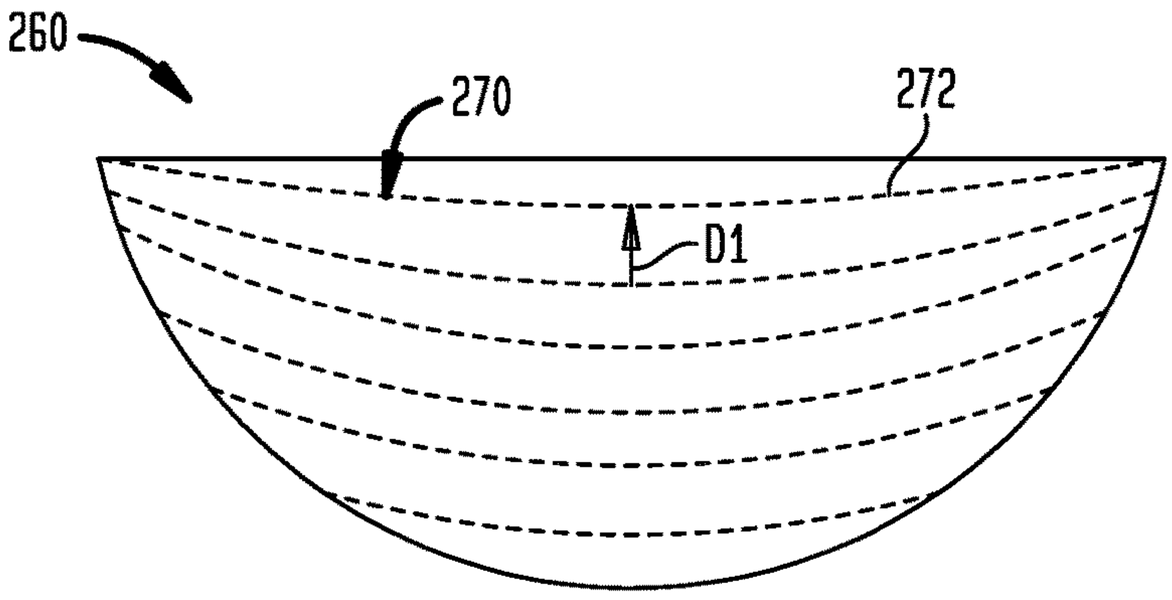


FIG. 2F

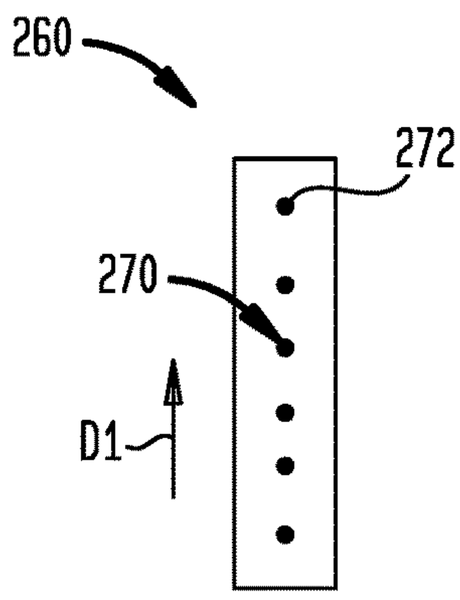


FIG. 3A

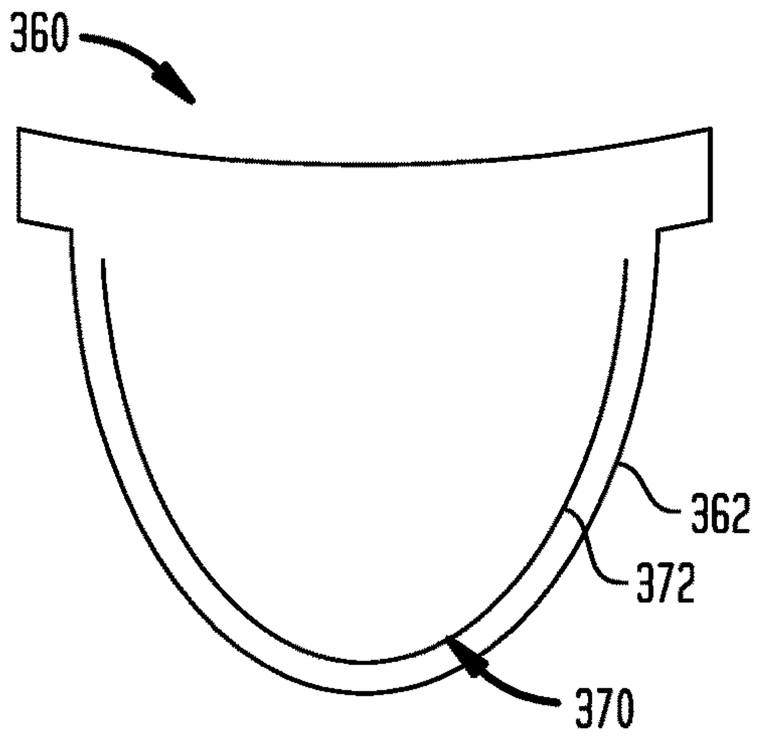


FIG. 3B

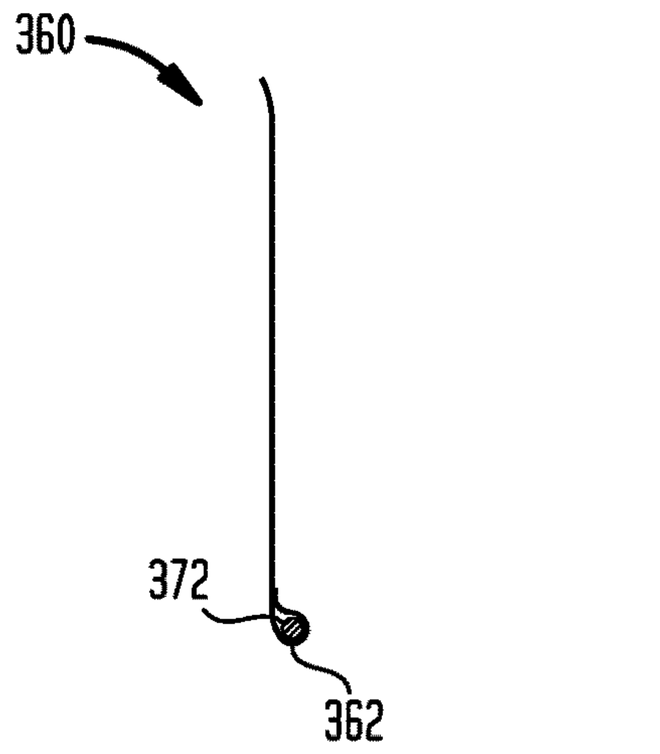


FIG. 3C

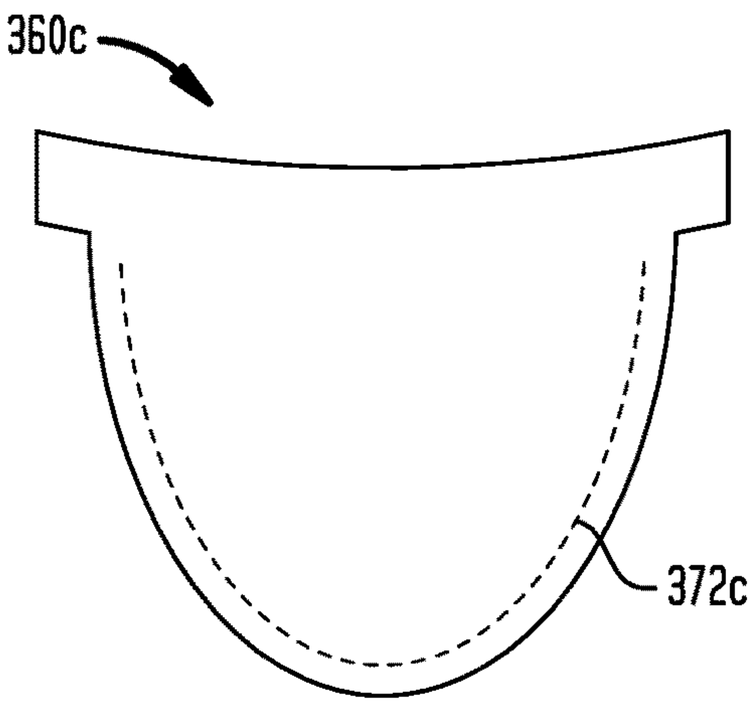


FIG. 3D

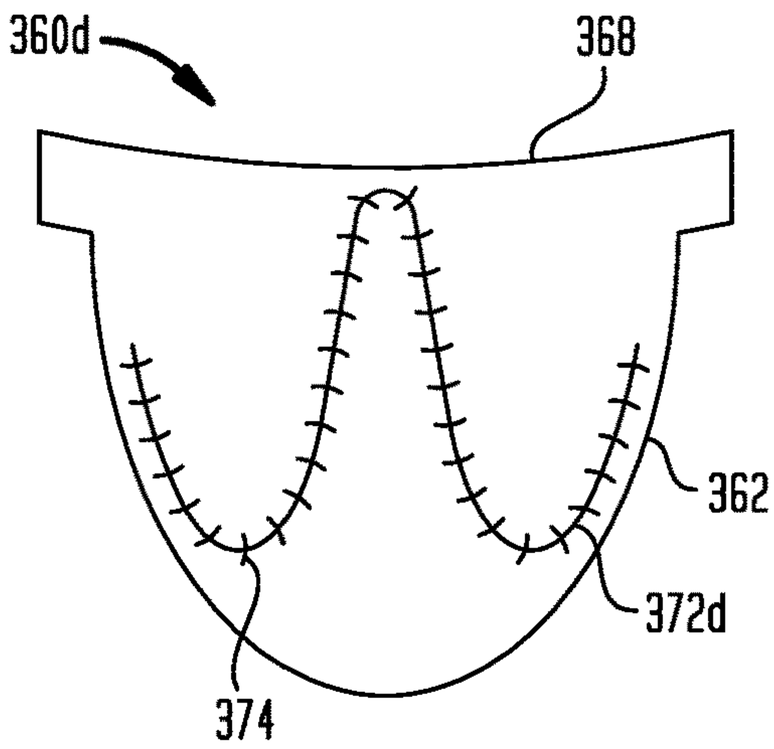


FIG. 3E

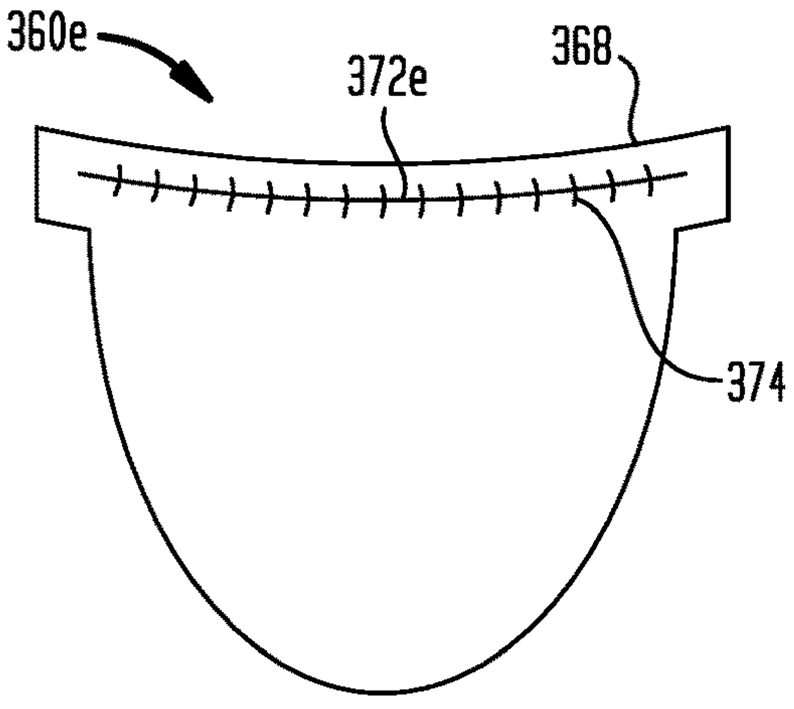


FIG. 3F

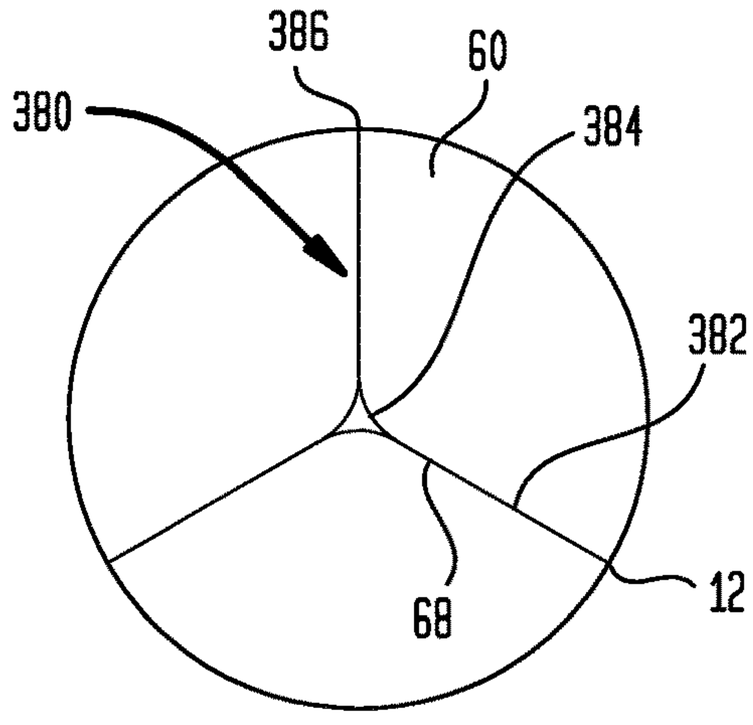


FIG. 4A

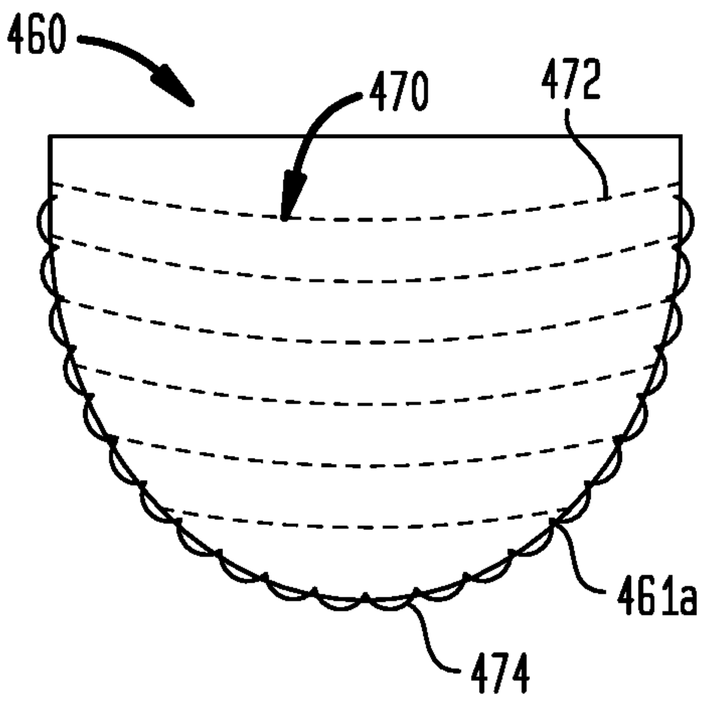


FIG. 4B

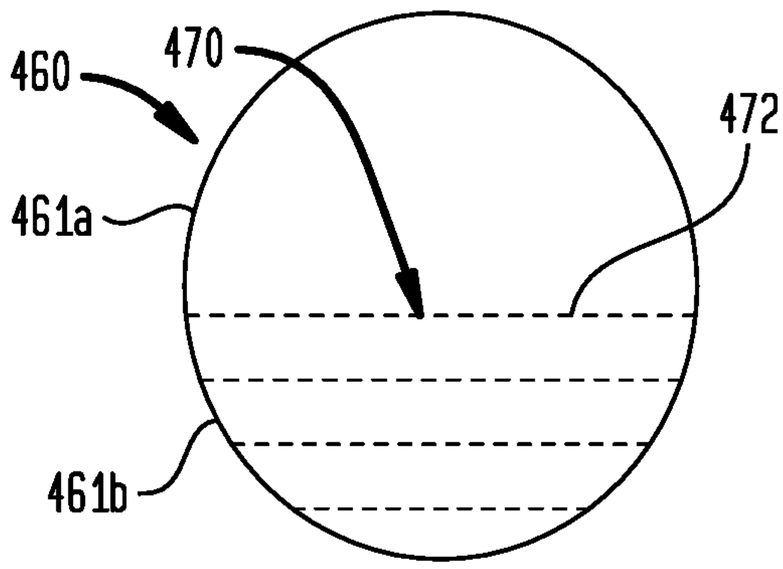


FIG. 4C

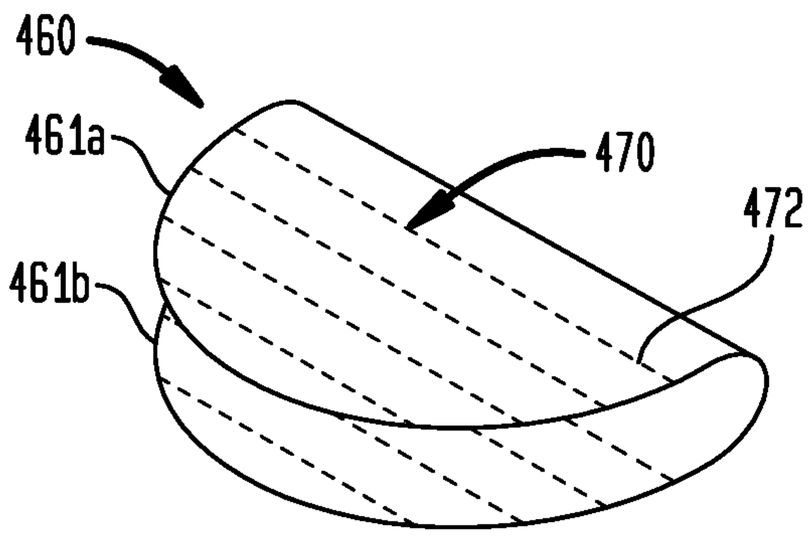


FIG. 5

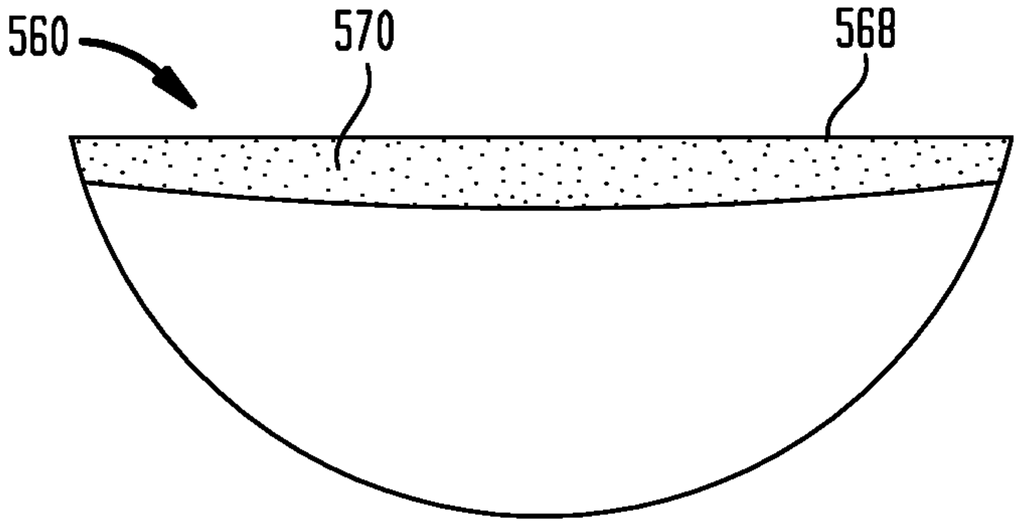


FIG. 6

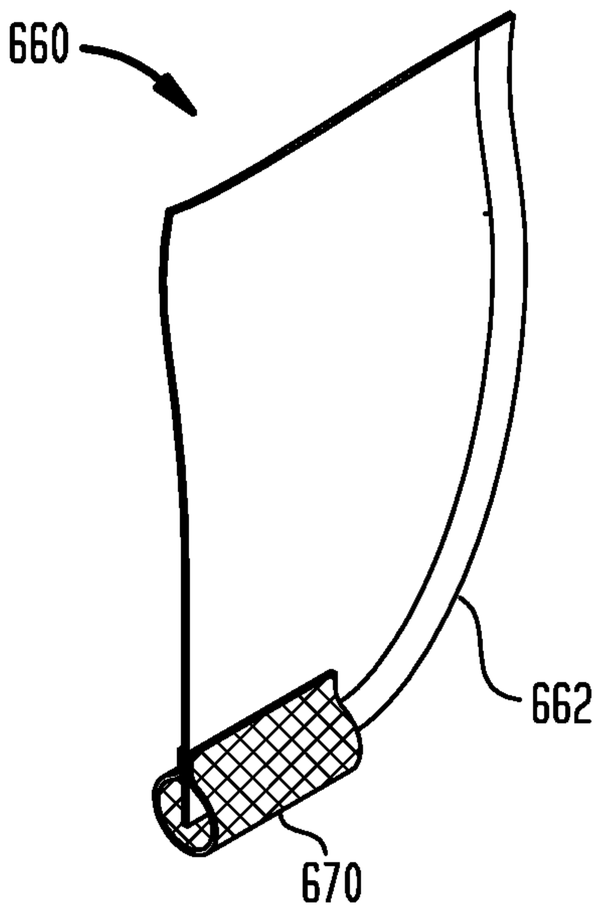


FIG. 7A

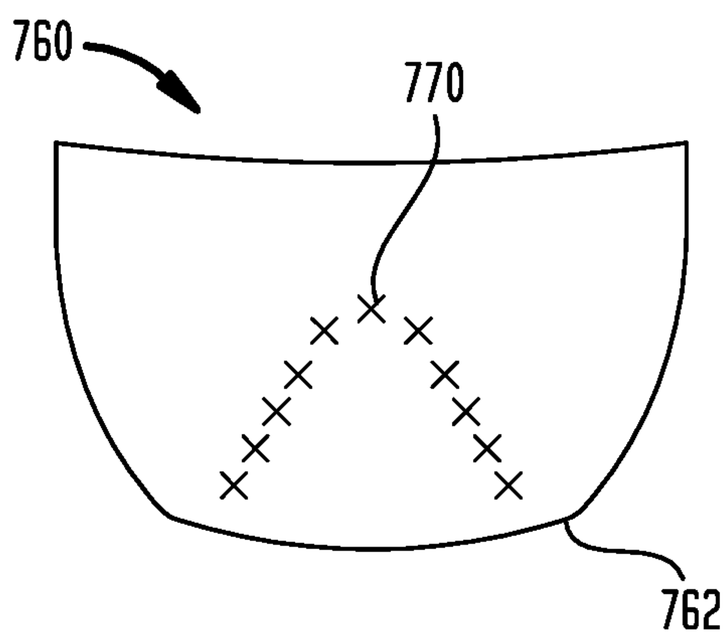


FIG. 7B

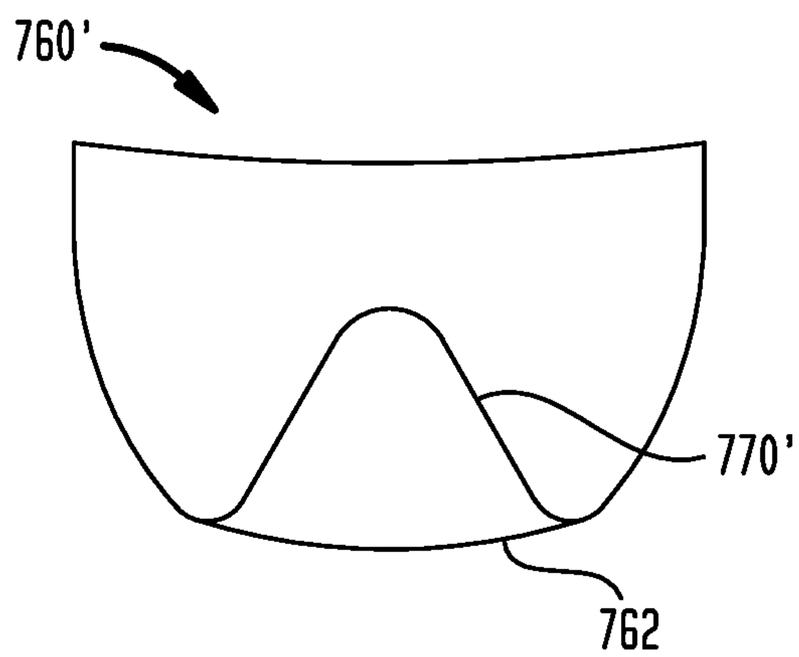


FIG. 8A

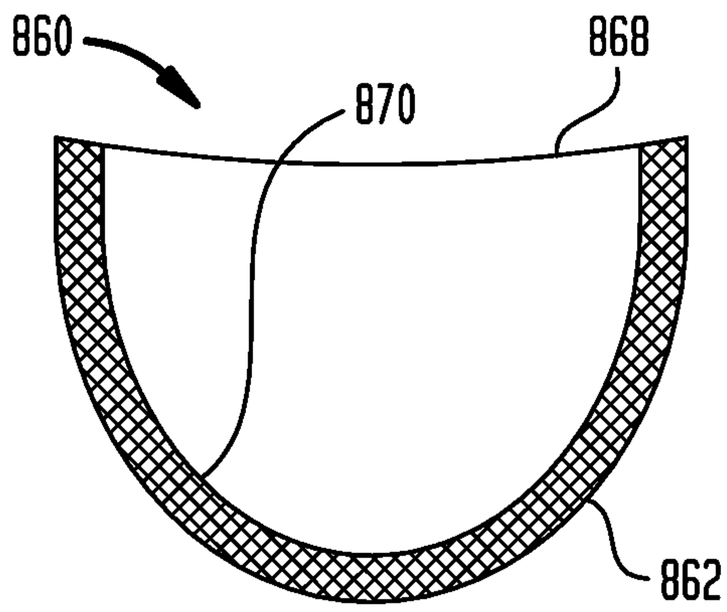


FIG. 8B

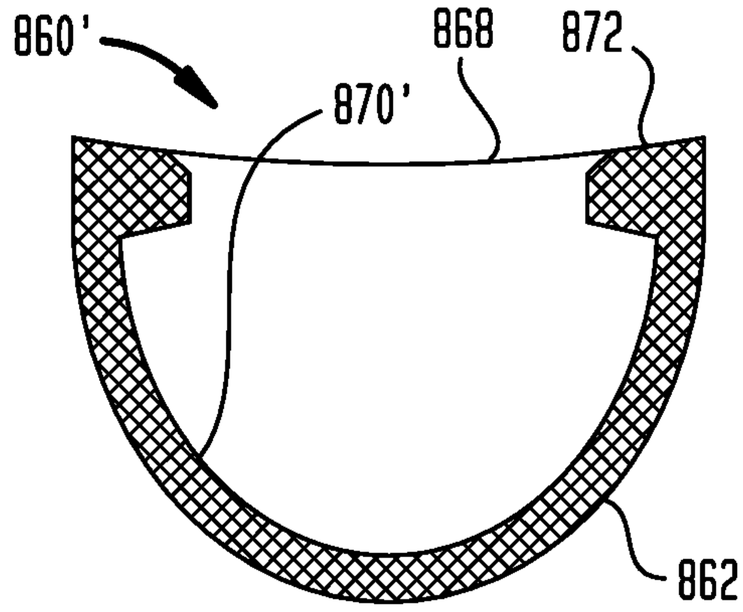


FIG. 8C

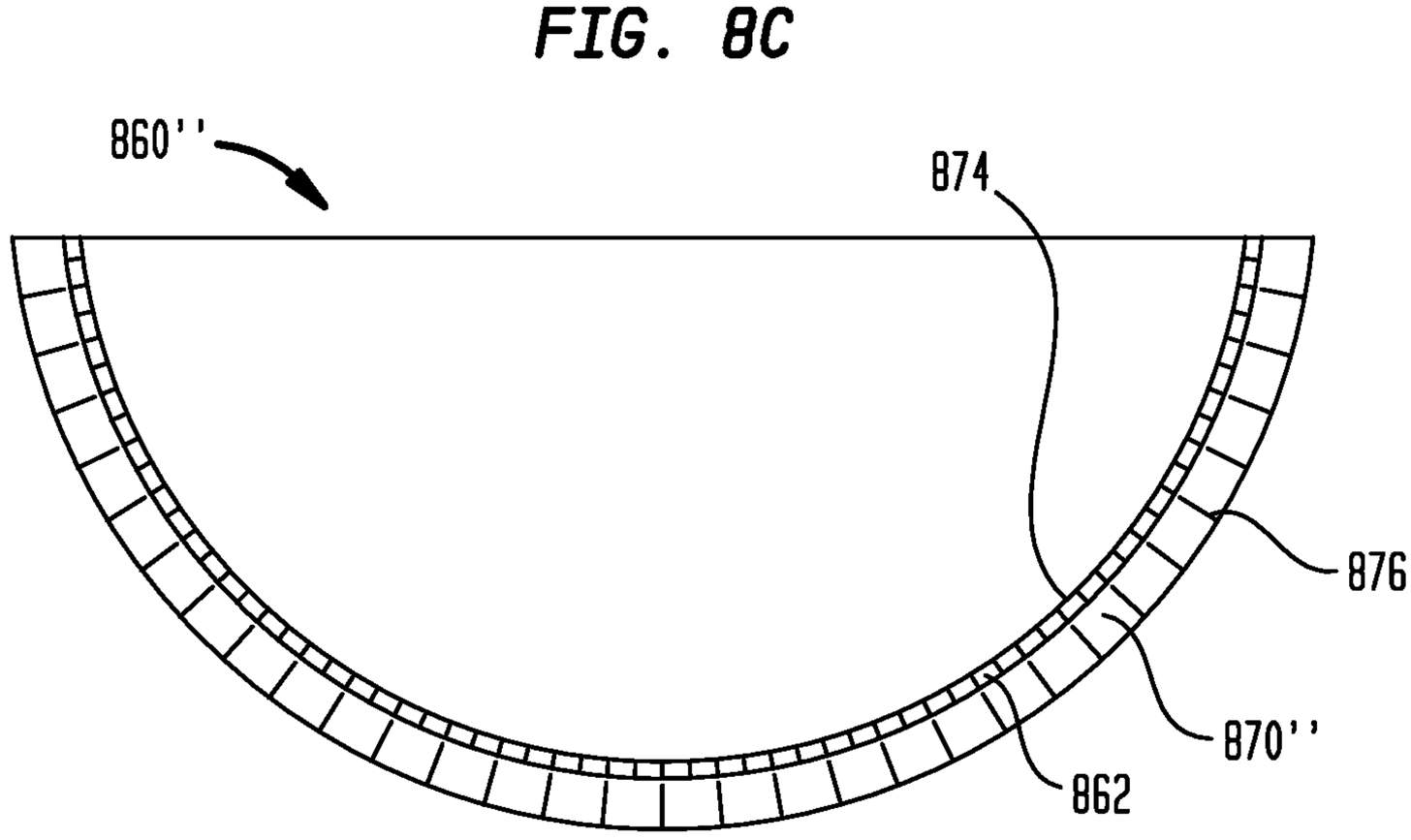


FIG. 9A

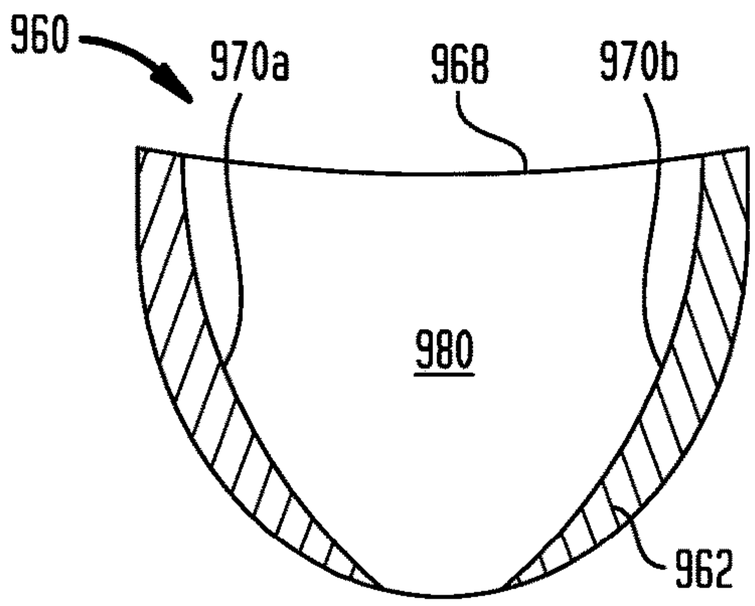


FIG. 9B

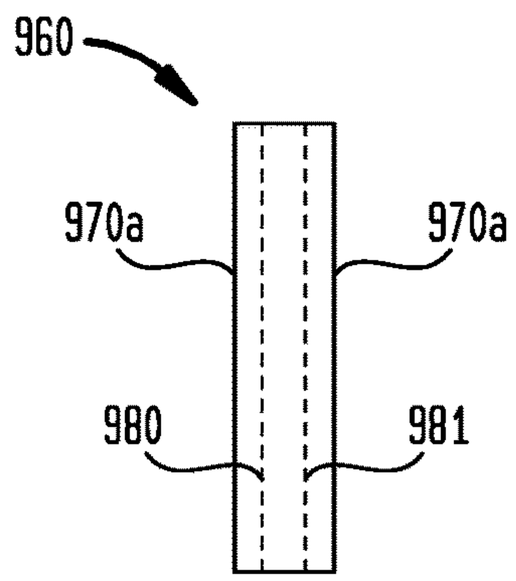


FIG. 10A

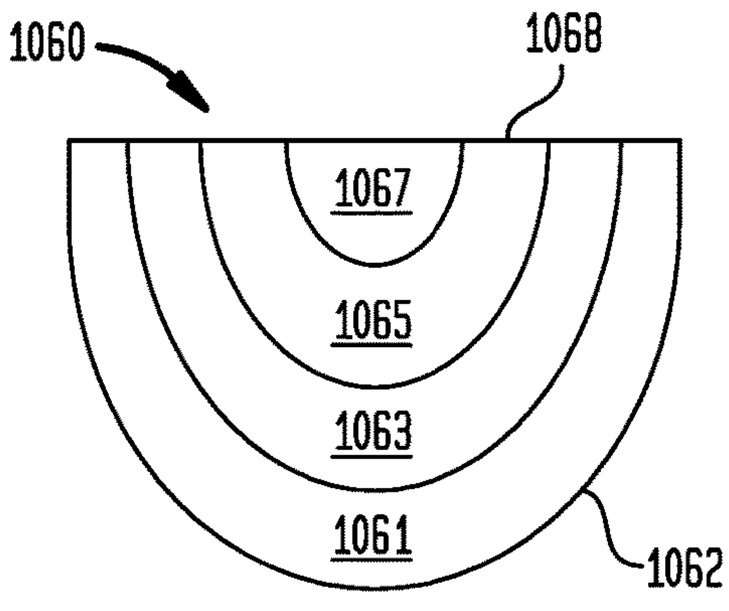


FIG. 10B

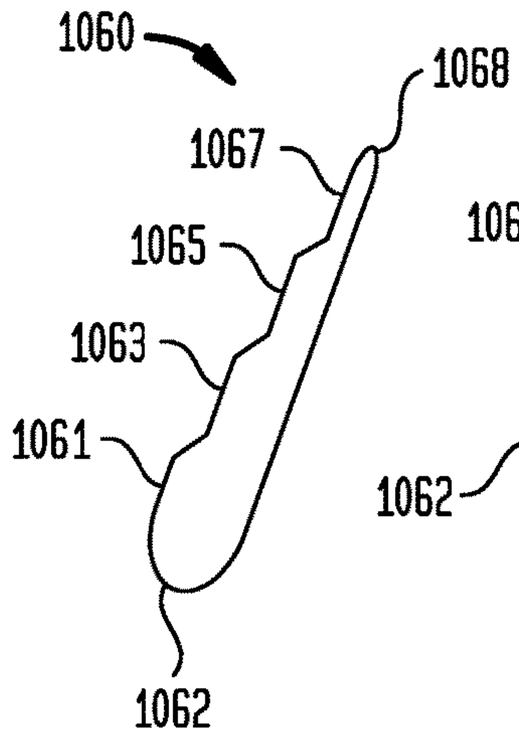


FIG. 10C

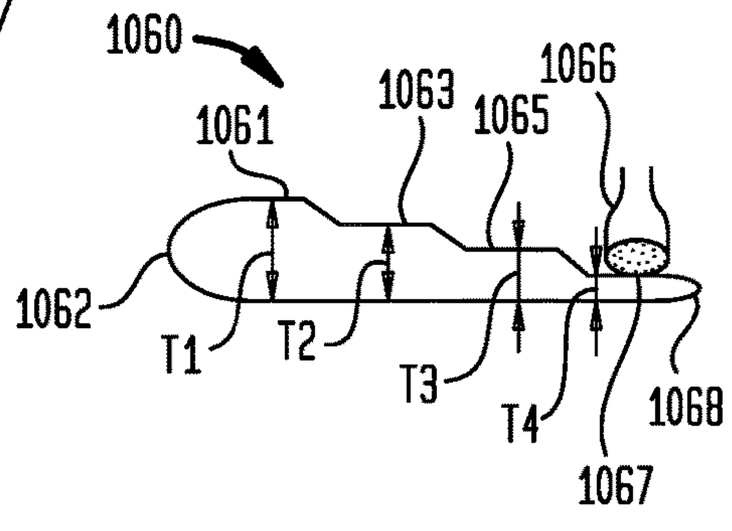
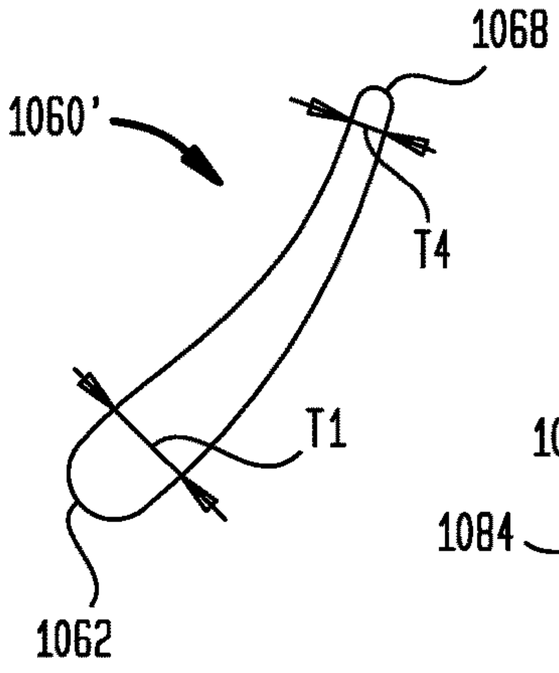


FIG. 10D



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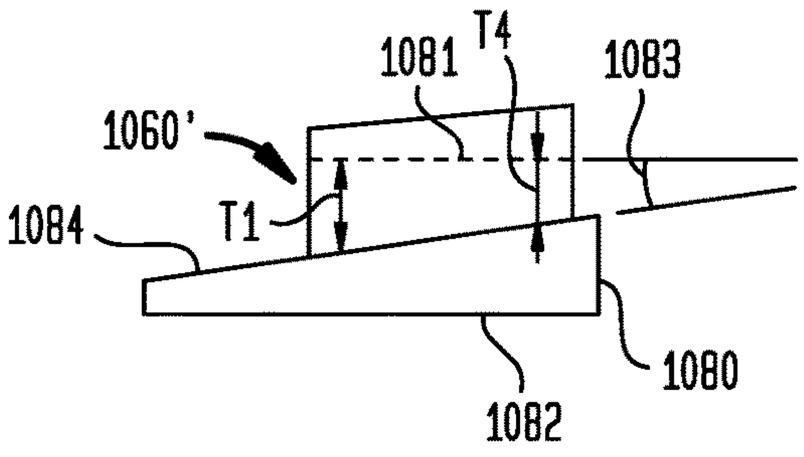


FIG. 10F

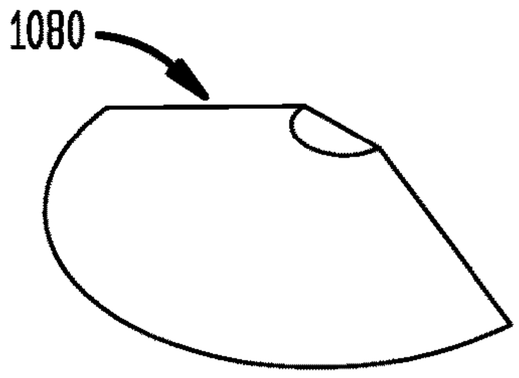
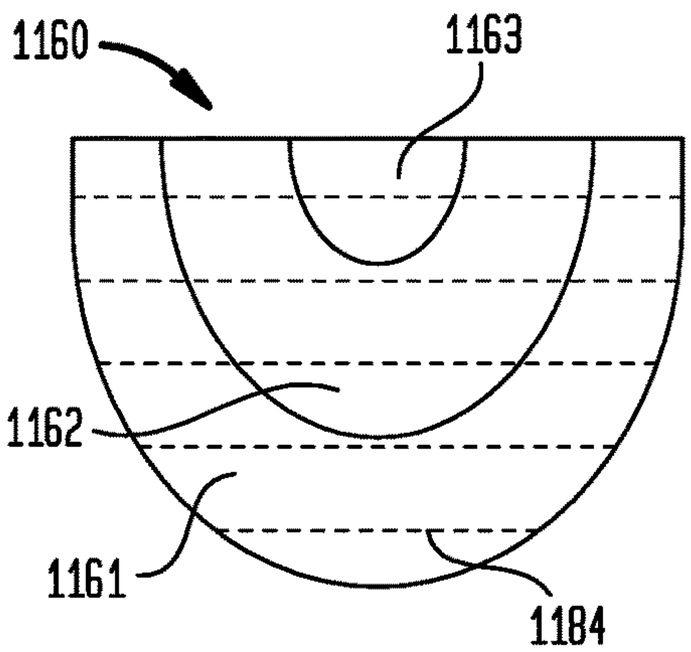


FIG. 11A



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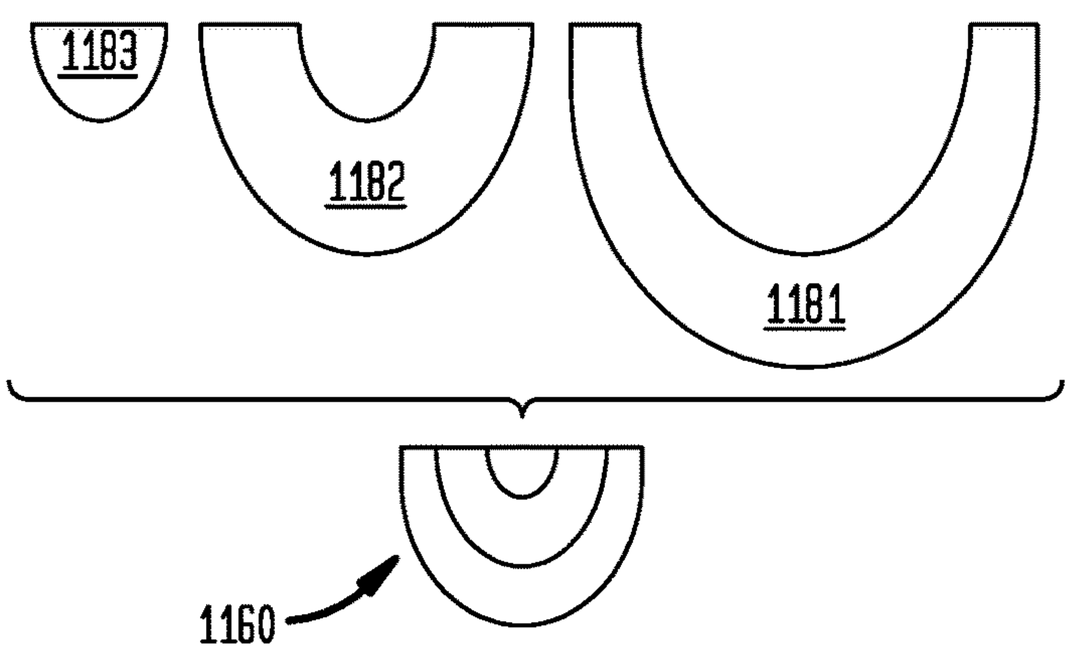
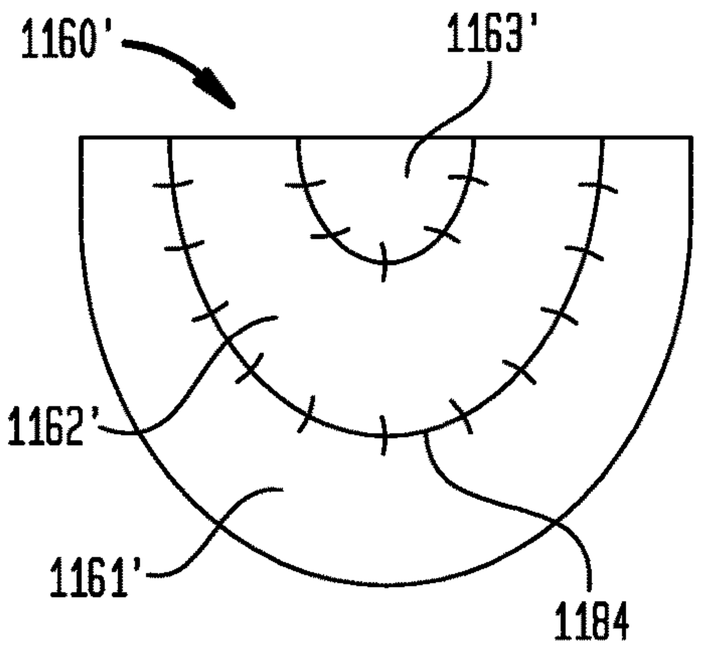


FIG. 11C



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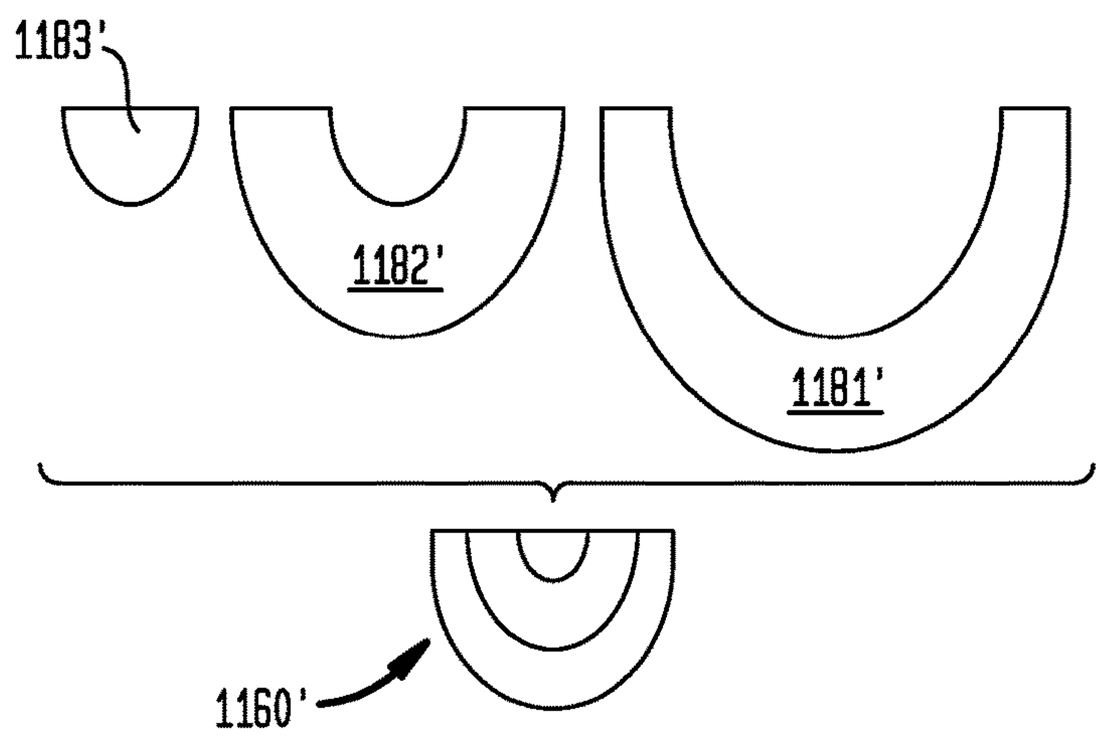
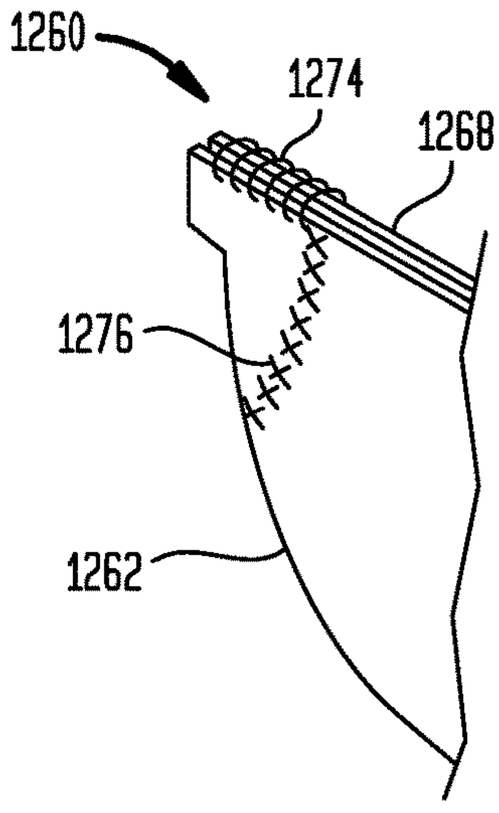


FIG. 12



COLLAPSIBLE LEAFLETS FOR PROSTHETIC HEART VALVES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of the filing date of U.S. Provisional Patent Application No. 63/008,245 filed Apr. 10, 2020, the disclosure of which is hereby incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present disclosure relates in general to heart valve replacement and, in particular, to prosthetic heart valves. More particularly, the present disclosure relates to leaflets for use in prosthetic heart valves.

Open-heart and transcatheter heart valve replacements are increasingly being performed in lower-risk patients. Such patients are typically younger than the higher-risk patient population that has traditionally received prosthetic heart valves, so they have a longer remaining life expectancy than traditional prosthetic heart valve recipients.

Prosthetic heart valves that are collapsible to a relatively small circumferential size can be delivered into a patient less invasively than valves that are not collapsible. For example, a collapsible valve may be delivered into a patient via a tube-like delivery apparatus such as a catheter, a trocar, a laparoscopic instrument, or the like. This collapsibility can avoid the need for a more invasive procedure such as full open-chest, open-heart surgery.

Collapsible prosthetic heart valves typically take the form of a valve structure mounted on a stent. There are two types of stents on which the valve structures are ordinarily mounted: a self-expanding stent and a balloon-expandable stent. To place such valves into a delivery apparatus and ultimately into a patient, the valve must first be collapsed or crimped to reduce its circumferential size.

When a collapsed prosthetic valve has reached the desired implant site in the patient (e.g., at or near the annulus of the patient's heart valve that is to be replaced by the prosthetic valve), the prosthetic valve can be deployed or released from the delivery apparatus and re-expanded to full operating size. For balloon-expandable valves, this generally involves releasing the entire valve, assuring its proper location, and then expanding a balloon positioned within the valve stent. For self-expanding valves, on the other hand, the stent automatically expands as the sheath covering the valve is withdrawn.

Despite the various improvements that have been made to collapsible prosthetic heart valves, conventional prosthetic heart valves suffer from some shortcomings. For example, in conventional collapsible prosthetic heart valves, the leaflets are typically made from biological tissue, such as porcine tissue. Over an extended patient lifespan, such biological leaflets may eventually erode or tear, creating a need for further surgical intervention or an additional valve replacement.

Biological leaflets may fail when excessively loaded or abraded. Biological leaflets have decent durability but may wear on the edges where they contact and coapt with one another and edges where they attach to the frame. Stresses in the tissue leaflets may limit valve durability by causing functional failures through tears or hole formation or acting as nodes for calcification initiation. Non-uniform or unbalanced leaflet coaptation may result in higher stresses in the leaflets, which may negatively impact valve durability.

There therefore is a need for further improvements to collapsible prosthetic heart valves. Among other advantages, the present invention may address one or more of these needs.

BRIEF SUMMARY OF THE INVENTION

The disclosure herein describes multiple embodiments of a prosthetic heart valve that include an expandable stent having an inflow end, an outflow end, an annulus section adjacent the inflow end, and a plurality of cells connected to one another in a plurality of annular rows around the stent; a cuff attached to the annulus section of the stent; a plurality of leaflets disposed within an interior region of the stent and attached to at least one of the cuff or the stent, the leaflets together having a coapted position occluding the interior region of the stent and an open position in which the interior region is not occluded, each leaflet including a primary leaflet material; and a support skeleton attached to the primary leaflet material of each leaflet, the support skeleton including a rigid reinforcing material having properties that are different from those of the primary leaflet material, such as a higher durometer than a durometer of the primary leaflet material.

Also described herein are multiple embodiments of a prosthetic heart valve that include an expandable stent having an inflow end, an outflow end, an annulus section adjacent the inflow end, and a plurality of cells connected to one another in a plurality of annular rows around the stent; a cuff attached to the annulus section of the stent; a plurality of leaflets disposed within an interior region of the stent and attached to at least one of the cuff or the stent, the leaflets together having a coapted position occluding the interior region of the stent and an open position in which the interior region is not occluded, each leaflet including a primary leaflet material; and a reinforcement attached to a surface of the primary leaflet material of each leaflet, the reinforcement including a material having properties that are different from those of the primary leaflet material, such as a higher durometer than a durometer of the primary leaflet material.

Further described herein are multiple embodiments of a prosthetic heart valve that include an expandable stent having an inflow end, an outflow end, an annulus section adjacent the inflow end, and a plurality of cells connected to one another in a plurality of annular rows around the stent; a cuff attached to the annulus section of the stent; a plurality of leaflets disposed within an interior region of the stent and attached to at least one of the cuff or the stent, the leaflets together having a coapted position occluding the interior region of the stent and an open position in which the interior region is not occluded, each leaflet including a primary leaflet material, and each leaflet having a thickness that varies from a belly of the leaflet to a free edge of the leaflet.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present invention will now be described with reference to the appended drawings. It is to be appreciated that these drawings depict only some embodiments of the invention and are therefore not to be considered limiting of its scope.

FIG. **1** is a side view of a conventional collapsible prosthetic heart valve;

FIG. **2**A is a plan view of one embodiment of a leaflet suitable for use with the collapsible prosthetic heart valve of FIG. **1**;

FIG. **2**B is a side view of the leaflet of FIG. **2**A;

FIG. **2**C is a plan view of three leaflets of FIG. **2**A shown in a coapted position;

FIG. **2**D is a plan view of a leaflet that is a variation of the leaflet of FIG. **2**A;

FIG. **2**E is a plan view of a leaflet that is another variation of the leaflet of FIG. **2**A;

FIG. **2**F is a side view of the leaflet of FIG. **2**E;

FIG. **3**A is a plan view of another embodiment of a leaflet suitable for use with the collapsible prosthetic heart valve of FIG. **1**;

FIG. **3**B is a side view of the leaflet of FIG. **3**A;

FIGS. **3**C, **3**D, and **3**E are plan views of leaflets that are variations of the leaflet of FIG. **3**A;

FIG. **3**F is a plan view of a fixed support configured for use with the collapsible prosthetic heart valve of FIG. **1**;

FIG. **4**A is a plan view of another embodiment of a leaflet suitable for use with the collapsible prosthetic heart valve of FIG. **1**;

FIG. **4**B is a plan view of the layers of the leaflet of FIG. **4**A, shown in an unassembled condition;

FIG. **4**C is a perspective view of the leaflet of FIG. **4**A, shown before the leaflet layers are stitched to one another;

FIG. **5** is a plan view of another embodiment of a leaflet suitable for use with the collapsible prosthetic heart valve of FIG. **1**;

FIG. **6** is a perspective view of a portion of another embodiment of a leaflet suitable for use with the collapsible prosthetic heart valve of FIG. **1**;

FIG. **7**A is a plan view of another embodiment of a leaflet suitable for use with the collapsible prosthetic heart valve of FIG. **1**;

FIG. **7**B is a plan view of a leaflet that is a variation of the leaflet of FIG. **7**A;

FIG. **8**A is a plan view of another embodiment of a leaflet suitable for use with the collapsible prosthetic heart valve of FIG. **1**;

FIG. **8**B is a plan view of a leaflet that is a variation of the leaflet of FIG. **8**A;

FIG. **8**C is a plan view of a leaflet that is another variation of the leaflet of FIG. **8**A;

FIG. **9**A is a plan view of another embodiment of a leaflet suitable for use with the collapsible prosthetic heart valve of FIG. **1**;

FIG. **9**B is a side view of the leaflet of FIG. **9**A;

FIG. **10**A is a plan view of another embodiment of a leaflet suitable for use with the collapsible prosthetic heart valve of FIG. **1**;

FIG. **10**B is a side view of the leaflet of FIG. **10**A;

FIG. **10**C is a side view of the leaflet of FIG. **10**A, shown with a shaver;

FIG. **10**D is a side view of a leaflet that is a variation of the leaflet of FIG. **10**A;

FIG. **10**E is a side view of an in-process stage of producing the leaflet of FIG. **10**D;

FIG. **10**F is a perspective view of the angled plate of FIG. **10**E;

FIG. **11**A is a plan view of a leaflet that is another variation of the leaflet of FIG. **10**A;

FIG. **11**B is a plan view of an in-process stage of making the leaflet of FIG. **11**A;

FIG. **11**C is a plan view of a leaflet that is a variation of the leaflet of FIG. **11**A;

FIG. **11**D is a plan view of an in-process stage of making the leaflet of FIG. **11**C; and

FIG. **12** is a perspective view of a pair of leaflets suitable for use with the collapsible prosthetic heart valve of FIG. **1**.

DETAILED DESCRIPTION

As used herein in connection with a prosthetic heart valve, the term "inflow end" refers to the end of the heart valve through which blood enters when the heart valve is functioning as intended, and the term "outflow end" refers to the end of the heart valve through which blood exits when the heart valve is functioning as intended. As used herein in connection with a prosthetic heart valve, the term "proximal" refers to the inflow end of the heart valve or to elements of the heart valve that are relatively close to the inflow end, and the term "distal" refers to the outflow end of the heart valve or to elements of the heart valve that are relatively close to the outflow end. Also as used herein, the terms "generally," "substantially," "approximately," and "about" are intended to mean that slight deviations from absolute are included within the scope of the term so modified.

When used to indicate relative locations within the prosthetic heart valve, the terms "longitudinal" and "vertical" are to be taken as the direction of the axis extending between the inflow end and the outflow end of the stent of the heart valve, along the direction of intended blood flow; the term "flow direction" is to be taken as the direction from the inflow end to the outflow end of the stent of the heart valve; and the terms "above," "below," "high," and "low" are to be taken as relative to the inflow end of the stent. "Above" and "high" are to be understood as relatively farther from the inflow end of the stent in the direction of intended blood flow, and "below" and "low" are to be understood as relatively closer to the inflow end of the stent in the direction of intended blood flow. When used to indicate relative locations within the prosthetic heart valve, the term "circumferential" is to be taken as the direction of rotation about the longitudinal axis of the stent.

FIG. **1** illustrates a collapsible and/or expandable stent-supported prosthetic heart valve **10** including a stent **12** and a valve assembly **14** as is known in the art. The prosthetic heart valve **10** is designed to replace a native heart valve of a patient, such as a native aortic valve, mitral valve, pulmonary valve, or tricuspid valve. It should be noted that while the example of FIG. **1** is described as a prosthetic aortic valve having a stent with a shape as illustrated, the valve could be a bicuspid valve, such as the mitral valve, and the stent could have different shapes, such as a flared or conical annulus section, a less-bulbous aortic section, and the like, and a differently shaped transition section between the annulus section and the aortic section. Any details of the structure and function of the prosthetic heart valve **10** that are not described herein may be found in U.S. Pat. No. 10,143,551, the entire disclosure of which is hereby incorporated by reference herein.

The stent **12** may be formed from biocompatible materials that are capable of self-expansion or expansion via a balloon, including, for example, shape memory alloys such as nitinol, or other suitable metals or polymers. The stent **12** extends from an inflow or annulus end **20** to an outflow or aortic end **22**, and includes an annulus section **30** adjacent the inflow end, a transition section **31**, and an aortic section **32** adjacent the outflow end. Each of the sections of stent **12** includes a plurality of struts **40** forming cells **42** connected to one another in one or more annular rows around the stent. For example, as shown in FIG. **1**, the annulus section **30** may have two annular rows of complete cells **42** and the aortic section **32** and the transition section **31** may each have one

or more annular rows of partial cells. The stent **12** may include one or more retaining elements **46** at the outflow end **22**, the retaining elements being sized and shaped to cooperate with female retaining structures (not shown) provided within a transcatheter delivery device.

The prosthetic heart valve **10** includes the valve assembly **14** preferably positioned in the annulus section **30** of the stent **12** and secured to the stent. The valve assembly **14** includes a cuff **50** and a plurality of leaflets **60** that collectively function as a one-way valve by coapting with one another. As a prosthetic aortic valve, the prosthetic heart valve **10** has three leaflets **60**. However, it will be appreciated that other prosthetic heart valves with which the leaflets of the present disclosure may be used may have a greater or lesser number of leaflets. Both the cuff **50** and the leaflets **60** may be wholly or partly formed of any suitable biological material (e.g., animal tissue such as pericardium tissue), fabric, or polymer that is impermeable to liquid such as, for example, polytetrafluoroethylene (PTFE), polyvinyl alcohol (PVA), ultra-high molecular weight polyethylene (UHMWPE), silicone, urethane, and the like. The cuff **50** and the leaflets **60** may be formed of the above materials or any of the additional materials described in the U.S. provisional patent application 62/902,044, the disclosure of which is hereby incorporated by reference herein.

The leaflets **60** may be attached along their belly portions to the cells **42** of the stent **12**, with the commissure between adjacent leaflets being attached to commissure attachment features **44**. As can be seen in FIG. **1**, each commissure attachment feature **44** may lie at the intersection of four cells **42**, two of the cells being adjacent one another in the same annular row, and the other two cells being in different annular rows and lying in end-to-end relationship. Each of the commissure attachment features **44** may include one or more eyelets that facilitate the suturing of the leaflet commissure to the stent **12**.

The leaflets **60** are configured to move between an open position and a closed position in which the leaflets occlude a central opening of the valve assembly **14**. The leaflets **60** are configured such that they are in the open position when the blood pressure at the annulus end **20** of the stent **12** is greater than the blood pressure at the aortic end **22**, and are in the closed position when the blood pressure at the aortic end is greater than the blood pressure at the annulus end.

The prosthetic heart valve **10** may be used to replace a native aortic valve, a surgical heart valve, a heart valve that has undergone a surgical procedure, or any other valve that it is desired to replace. The prosthetic heart valve **10** may be delivered to the desired site (e.g., near or proximate a native valve annulus, or near or proximate an annuloplasty ring or other repair device) using any suitable delivery device.

During delivery, the prosthetic heart valve **10** may be disposed inside a transcatheter delivery device in a collapsed condition. The delivery device may be introduced into a patient using a transfemoral, transapical, transseptal, transradial, transsubclavian, transaortic or any other percutaneous approach. Once the delivery device has reached the target site, the user may deploy the prosthetic heart valve **10**. Upon deployment, the prosthetic heart valve **10** expands so that the annulus section **30** is in secure engagement within the native valve annulus (or in engagement with an annuloplasty ring or other repair device). When the prosthetic heart valve **10** is properly positioned, it works as a one-way valve, allowing blood to flow in the flow direction, and preventing blood from flowing in the opposite direction.

Prosthetic valve leaflets bear stress when loaded during valve opening and coaptation. The leaflet variations that will be described below with reference to FIGS. **2**A through **7**B may redistribute or reduce the load borne by the primary material of these leaflets when the leaflets move back and forth between an open position and a coapted position.

FIGS. **2**A-**2**C illustrate a leaflet **160** according to an embodiment of the invention that may replace each of the leaflets **60** described above with reference to the prosthetic heart valve **10**. The leaflet **160** may have the same function and shape as the leaflets **60**. The leaflets **160** may be attached along their belly **162** to the cells **42** of the stent **12** of FIG. **1**, with the commissure **164** between adjacent leaflets being attached to respective ones of the commissure attachment features **44**. The leaflets **160** may be attached to the stent **12** and/or the cuff **50** using one or more sutures. The leaflets **160** may have a primary leaflet material that is derived from animal tissue (i.e., pericardium) or other compatible materials (such as fabric or polymers).

The leaflet **160** may have an internal skeleton **170** having ribs **172** that are made of a rigid or semi-rigid reinforcing material extending within the primary leaflet material through an interior volume **166** of the leaflet. The internal skeleton **170** may be formed of a biocompatible metal, such as nitinol, or a more flexible material, such as suture or other polymer. In some examples, the internal skeleton **170** may be formed of a braided wire material that is not made of metal, but that has rigidity similar to that of a metal wire. Other materials may be used, but it is desirable that such materials exhibit superelasticity or otherwise be able to bend substantially in order to effectively collapse the leaflets into a delivery device. It is desirable that the material of the internal skeleton **170** be elastic, to assist with valve opening, but soft enough (low durometer) so as not to inhibit leaflet closing. The ribs **172** may have a shape memory, such that the ribs are in a stress-free state when the leaflets **160** are closed, and the ribs are storing energy when the leaflets are in an open position so that they bias the leaflets towards a coapted position. In this way, the ribs **172** may actively assist leaflet coaptation. The internal skeleton **170** may include a rigid or semi-rigid reinforcing material having certain properties that are different from the properties of the primary leaflet material. For example, the reinforcing material may have a higher durometer than the durometer of the primary leaflet material, but not so high as to interfere with coaptation.

The ribs **172** of the internal skeleton **170** may lie within the interior volume **166** of the leaflet **160** and may be spaced apart from one another in a direction D**1** that is parallel to an outer surface of the leaflet. Each rib **172** may have a roughened outer surface to reduce relative motion between the rib and the primary leaflet material, thereby promoting healing between the ribs and the primary leaflet material after implantation. Each of the ribs **172** may have a relatively small diameter compared to a thickness of the leaflet **160**, so that structural integrity of the primary leaflet material is not compromised. For example, each rib **172** may have a diameter of between about 0.002 inches and about 0.020 inches.

When the ribs **172** of the internal skeleton **170** are embedded within the interior volume **166** of the leaflet **160**, the material of the leaflet completely surrounds the ribs and holds them in place at fixed positions. However, in some embodiments the ribs **172** may be only partially embedded within the interior volume **166** of the leaflet **160**, such as by being woven between the fibers of the leaflet fabric, or may be disposed on the outer surface of the leaflet. When the ribs **172** are woven between the fibers of the leaflet **160** so as to be exposed on both the top and bottom surfaces of the leaflet,

the ribs may be held in place by heat sealing or welding together the interlaced fibers of the leaflet fabric immediately adjacent opposite sides of each rib. Heat sealing or welding these fibers together prevents the fibers from moving relative to one another, thereby trapping each rib **172** at a fixed position.

The ribs **172** may also be secured to the outer surface of the leaflet **160**. One method of securing the ribs **172** to the leaflet **160** is to apply transverse strips of fabric (not shown) across each rib at spaced locations along the length of the rib. The strips of fabric may be heat sealed or welded to the leaflet **160** on opposite sides of the rib **172**, holding the rib securely in place. The strips of fabric may be formed of the same material as forms the leaflet **160** or may be formed of a different material that can be easily heat sealed or welded to bond the strips to the leaflet. In an alternate arrangement, when the materials forming leaflet **160** and ribs **172** allow, the ribs may be directly heat sealed or welded to the leaflet without the use of ancillary strips of fabric.

Each of the ribs **172** may be bowed to a radius of curvature between that of a free edge **168** of the respective leaflet **160** and the belly **162**. One or more of the ribs **172** may extend out of the interior volume **166** of the leaflet to form extensions **174**. Each rib **172** may have an extension **174** extending out of the interior volume **166** at one end or both opposite ends of the rib. In one example, the extensions **174** may be attached to connectors (not shown) that could be coupled to the commissure attachment features **44**.

One possible reinforcing layout of the internal skeleton **170** is depicted in FIGS. **2**A-**2**C, although other orientations can be envisioned. In some instances, finite element analysis (FEA) could guide reinforcement layouts to target high-stress regions in the primary leaflet material. The layout of the internal skeleton **170** could also be oriented to incorporate material anisotropy (or alignment) in order to mimic native leaflet tissue.

FIG. **2**D shows another possible reinforcing layout that is a variation of the embodiment of FIGS. **2**A-**2**C, in which an internal skeleton **170'** comprises a plurality of ribs **172'** that are oriented in a direction that is generally perpendicular to the direction in which the ribs **172** of FIGS. **2**A-**2**C are oriented. The ribs **172'** extend from the belly **162** of the leaflet **160'** towards the free edge **168**, and may be attached to the leaflet **160'** using any of the arrangements described above for attaching the ribs **172** to the leaflets **160**. The ribs **172'** extend generally perpendicular to the free edge **168** of the leaflet **160'** and may be spaced apart from one another in a direction D**2** that is parallel to an outer surface of the leaflet. Each rib **172'** may be attached to the stent **12** and/or the cuff **50** at the belly **162** using a suture **174'**. In one example, a rigid reinforcing material may be used for the ribs **172'**. In this configuration, the leaflet **160'** may have reduced bending while opening and closing compared to the leaflet **160**. The internal skeleton **170'** may include a rigid or semi-rigid reinforcing material having certain properties that are different from the properties of the primary leaflet material. In one example, the reinforcing material may have a higher durometer than a durometer of the primary leaflet material, but not so high as to interfere with coaptation.

FIGS. **2**E and **2**F show a leaflet **260**, which is another variation of the leaflet **160**, in which a solvent may be applied to the primary material of the leaflet, thereby creating reinforcing ribs **272** of the primary leaflet material that are more rigid than the surrounding primary leaflet material. The solvent may be applied to the primary leaflet material using various methods, including, but not limited to, injection, wicking, and soaking. After achieving adequate distribution of the solvent through the primary leaflet material, the solvent may be cured, for example, via drying or ultraviolet exposure.

The resulting internal skeleton **270** may have a rib structure similar to the internal skeleton **170** or **170'**, but the rib structure would be achieved by application of the solvent to form ribs **272** in place of the insertion of ribs **172** or **172'** of a more rigid material into the primary leaflet material. In such a variation, the internal skeleton pattern achieved may have more ribs **272** that are spaced closer together than the ribs **172** or **172'**, thereby potentially evening out the stress experienced across the leaflet **260**, but without compromising the structural integrity of the primary leaflet material. The ribs **272** may be spaced apart from one another in a direction D**1** that is parallel to an outer surface of a respective one of the leaflets **260**.

FIGS. **3**A and **3**B illustrate a leaflet **360** according to an embodiment of the invention that may replace each of the leaflets **60** described above with reference to the prosthetic heart valve **10**. The leaflet **360** is another variation of the leaflet **160** described above. The leaflet **360** may be the same as the leaflet **160**, except that its internal skeleton **370** has a single rib **372** that extends along the belly **362**, and the rib is secured to the primary leaflet material by having the edge of the belly wrapped around the rib as shown in FIG. **3**B. The rib **372** may be made of a thin wire of nitinol, an MP35 nickel-based alloy, a spring metal, stainless steel, cobalt, or any of the other materials mentioned above with respect to the leaflet **160**. The rib **372** may be heat set to introduce a bias to retain a desired shape with shape memory. To retain the rib **372** within the primary leaflet material, the primary leaflet material may be sealed to itself with heat sealing, an adhesive, sutures or another known sealing mechanism. The internal skeleton **370** may include a rigid reinforcing material having certain properties that are different from those of the primary leaflet material, such as a higher durometer than a durometer of the primary leaflet material, but not so high as to interfere with coaptation.

The rib **372** may assist the primary leaflet material in keeping a desired shape, which may shorten the timing of coaptation of the leaflets **360**, and improve the consistency of coaptation, robustness of the leaflets to wear, and balance of coaptation (i.e., all three leaflets coapting at the same time). This latter feature may prevent one of the leaflets from experiencing wear faster than the other leaflets.

The leaflet **360***c* shown in FIG. **3**C is similar to the leaflet **360**, except that the leaflet **360***c* includes a single rib **372***c* that is threaded through the primary leaflet material in a manner similar to a suture, so it is not necessary to have the edge of the belly wrapped around the rib as shown in FIG. **3**B. The rib **372***c* may be held securely in place on the leaflet **360***c* by heat sealing or welding the fibers together along opposite sides of the rib in the manner described above in connection with the ribs **172**.

The leaflet **360***d* shown in FIG. **3**D is also similar to the leaflet **360**, except that the leaflet **360***d* includes a single rib **372***d* that has a serpentine shape with ends adjacent to the belly **362** at opposite ends of the belly, and a central portion that extends across the middle of the leaflet to reach a location adjacent to the center of the free edge **368** of the leaflet. The serpentine shape of the rib **372***d* may exhibit an improvement in balanced coaptation over the rib **372**. The rib **372***d* may be sutured to a surface of the primary leaflet material by sutures **374**. Alternatively, the rib **372***d* may be attached to the surface of the leaflet **360***d* by heat sealing or welding fabric strips across the rib to the leaflet **360***d* in the manner described above in connection with ribs **172**. In still

a further arrangement, rib **372***d* may be heat sealed or welded directly to the leaflet when the materials of the leaflet and rib allow for such procedure.

The leaflet **360***e* shown in FIG. **3**E is similar to the leaflet **360***d*, except that the leaflet **360***e* includes a single rib **372***e* that extends along the free edge **368** of the leaflet. The location of the rib **372***e* adjacent to the free edge **368** may result in an improvement in balanced coaptation over the rib **372**, and this location may help prevent the free edge from fluttering and may help limit the range of motion of the free edge to prevent contact with the struts **40** of the stent **12**. The rib **372***e* may be sutured to a surface of the primary leaflet material by sutures **374** or may be threaded or woven through the primary leaflet material. The rib **372***e* may be secured in place on the leaflet **360***e* by heat sealing or welding the fibers of the leaflet material on opposite sides of the rib. The rib **372***e* may also be joined to the leaflet **360***e* by heat sealing or welding strips of fabric across the rib as described above in connection with ribs **172**. Still further, when the materials of the leaflet and rib allow, the rib may be heat sealed or welded directly to the leaflet.

FIG. **3**F illustrates a fixed support **380** having three struts **382** that may be added to the prosthetic heart valve **10** by suspending it in a central opening of the prosthetic heart valve **10** at a location where the leaflets **60** coapt. The struts **382** may be made of a thin wire of nitinol, an MP35 nickel-based alloy, a spring metal, stainless steel, cobalt, or any of the other materials mentioned above with respect to the leaflet **160**. The struts **382** may have first ends **384** coupled to one another at a central location within the central opening of the prosthetic heart valve **10** and second ends **386** attached to the stent **12** and/or the cuff **50** of FIG. **1**. The fixed support **380** may be configured so that the free edges **68** of the leaflets **60** coapt against it, and the location of the fixed support may assist the leaflets **60** to exhibit more balanced coaptation.

FIGS. **4**A-**4**C illustrate a leaflet **460** according to an embodiment of the invention that may replace each of the leaflets **60** described above with reference to the prosthetic heart valve **10**. The leaflet **460** is another variation of the leaflet **160** described above. The leaflet **460** may be similar to the leaflet **160**, except that the ribs **472** of its internal skeleton **470** are disposed between two leaflet layers **461***a*, **461***b* rather than extending within the primary leaflet material.

In the embodiment shown, leaflet layers **461***a* and **461***b* may be two portions of a single sheet of leaflet material (FIG. **4**B) that are folded over one another (FIG. **4**C) and then fixed together (FIG. **4**A) to enclose the ribs **472**. Sutures **474** may be used to stitch the two leaflet layers **461***a*, **461***b* together. The application of the sutures **474** may be done at the same time as the attachment of the leaflet **460** to the stent **12** and/or the cuff **50** of the prosthetic heart valve **10**. Alternatively, leaflet layers **461***a*, **461***b* may be joined by adhesive, heat lamination, ultrasonic welding, or other known joining techniques. To ensure the ribs **472** do not move between the layers of leaflet material, each of these joining techniques, including suturing, should be performed adjacent opposite sides of each rib, as well as at other locations at which the layers may be joined together.

In other examples, the leaflet layers **461***a* and **461***b* may be separate elements that are laminated, glued, sutured or otherwise joined to one another on opposite sides of the internal skeleton. Any of various biocompatible materials may be used for the leaflet layers **461***a*, **461***b*, such as pericardium tissue, polyurethane sheets, fabric, and the like.

The concept of sandwiching the ribs **472** of the internal skeleton **470** between two leaflet layers **461***a*, **461***b* may be applied to any configuration of ribs that is disclosed herein. Specifically, the internal skeleton **470** may be replaced with the internal skeleton **170** of FIGS. **2**A-**2**C, the internal skeleton **170'** of FIG. **2**D, the internal skeleton **370** of FIGS. **3**A and **3**B, or the variations of the rib geometries shown in FIGS. **3**C-**3**E.

FIG. **5** illustrates a leaflet **560** according to an embodiment of the invention that may replace each of the leaflets **60** described above with reference to the prosthetic heart valve **10**. The leaflet **560** may be similar to the leaflet **60**, except that the leaflet **560** has a reinforcement **570** disposed at the free edge **568**. For example, the primary leaflet material of the leaflet **560** may be pericardial tissue, and the reinforcement **570** may be a strip-shaped sheet of material (e.g., a metal such as nitinol or a semi-rigid polymer) that is applied to one or both of the external surfaces of the primary leaflet material adjacent the free edge **568**. The reinforcement **570** may reinforce the primary leaflet material of the leaflet **560** at the coaptation zone to reduce the bending stress at the free edge **568** during leaflet coaptation. The reinforcement **570** may be attached to one or both external surfaces of the primary leaflet material using an adhesive, for example, or other joining techniques including heat lamination and ultrasonic welding. The reinforcement **570** may include a material having properties that are different from those of the primary leaflet material, such as a higher durometer than a durometer of the primary leaflet material, but not so high as to interfere with coaptation.

FIG. **6** illustrates a portion of a leaflet **660** according to an embodiment of the invention that may replace each of the leaflets **60** described above with reference to the prosthetic heart valve **10**. The leaflet **660** may be similar to the leaflet **60**, except that the leaflet **660** has a reinforcement **670** attached to a part of the belly **662** of the leaflet, at a location at which the leaflet is closest to the stent **12** and/or the cuff **50** of the prosthetic heart valve **10**. The reinforcement **670** may comprise a material having properties that are different from those of the primary leaflet material, such as a higher elasticity than the primary leaflet material, so that strain within the primary leaflet material may be reduced. The reinforcement **670** may comprise reinforced silicones, urethanes, or a fabric such as Dacron, among other materials. The reinforcement **670** may include a material having other properties different from those of the primary leaflet material, such as a higher durometer than a durometer of the primary leaflet material, but not so high as to interfere with coaptation.

The reinforcement **670** may extend along an edge of the belly **662** of the leaflet **660**, with a portion of the reinforcement attached to the leaflet. The remainder of the reinforcement **670** may extend beyond the edge of the belly **662** of the leaflet **660**, so only the material of the reinforcement is directly attached to the stent **12** and/or the cuff **50**. In other examples (not shown), the reinforcement **670** may not extend beyond the edge of the belly **662** of the leaflet **660**, so that there may be direct contact between the primary leaflet material and the stent **12** and/or the cuff **50**. The reinforcement may be attached to the material of the leaflet by any of the techniques noted previously, including adhesive, heat lamination, ultrasonic welding or suturing. Regarding the attachment of the leaflet **660** to the stent **12** and/or the cuff **50**, there are a few ways that the reinforcement **670** and the edge of the belly **662** can be arranged. In one, example the reinforcement **670** may lie on top of the leaflet **660** and sutures may extend through the leaflet and

the reinforcement to attach the leaflet to the stent **12** and/or the cuff **50**. In another example, the reinforcement **670** may wrap around the edge of the belly **662** so that one portion is on top of the leaflet and another portion is on the bottom of the leaflet, and sutures may extend though both the leaflet and the two portions of the reinforcement for attachment to the stent **12** and/or the cuff **50**. Alternatively, the sutures may extend only through the two portions of the reinforcement **670** for attachment to the stent **12** and/or the cuff **50** without extending though the belly **662** of the leaflet **660**.

FIGS. **7**A and **7**B illustrate leaflets **760** and **760'** according to embodiments of the invention that may replace each of the leaflets **60** described above with reference to the prosthetic heart valve **10**. The leaflet **760** may be similar to the leaflet **60**, except that the leaflet **760** includes reinforcements **770** in the form of sutures or other stitches in a central region of the leaflet extending towards the belly **762**. The reinforcements **770** may provide a surface feature that is more resistant to abrasion than the primary leaflet material. As shown in FIG. **7**A, the reinforcements **770** may form an inverted U or V shape extending from a central region of the leaflet towards the belly **762**. However, in other examples, the specific shape or pattern of the reinforcements **770** may be adjusted to provide reinforcement in regions of the leaflet **760** that are most susceptible to abrasion. The reinforcements **770** (e.g., the sutures or other stitches) may include a material having a higher durometer than a durometer of the primary leaflet material, but not so high as to interfere with coaptation, or other properties that are different from those of the primary leaflet material.

The leaflet **760'** shown in FIG. **7**B is a variation of the leaflet **760** that may be similar to the leaflet **60**, except that the leaflet **760'** includes a reinforcement **770'** in the form of a fabric attached to a surface of the primary leaflet material in a central region of the leaflet extending towards the belly **762**. The reinforcement **770'** may be an ultra-thin low density fabric or a similar material that is more resistant to abrasion than the primary leaflet material. As shown in FIG. **7**B, the reinforcement **770'** may have an inverted U or V shape extending from a central region of the leaflet towards the belly **762**. However, in other examples, the specific shape of the reinforcement **770'** may be adjusted to provide reinforcement in regions of the leaflet **760'** that are most susceptible to abrasion. The reinforcement **770'** may include a material having certain properties that are different from the properties of the primary leaflet material. For example, the reinforcement may have a higher durometer than a durometer of the primary leaflet material, but not so high as to interfere with coaptation. The reinforcement **770'** may attached to the leaflet **760'** by heat lamination, ultrasonic welding, suturing or other known techniques.

FIGS. **8**A and **8**B illustrate leaflets **860** and **860'** according to embodiments of the invention that may replace each of the leaflets **60** described above with reference to the prosthetic heart valve **10**. The leaflet **860** may be similar to the leaflet **60**, except that the leaflet **860** includes a reinforcement **870** attached to a surface of the primary leaflet material extending across the belly **862** of the leaflet, at locations at which the leaflet may be sewn to the stent **12** and/or the cuff **50** of the prosthetic heart valve **10**. The reinforcement **870** may provide additional strength and suture retention support in addition to the primary leaflet material. The reinforcement **870** may include a material having a higher durometer than a durometer of the primary leaflet material, but not so high as to interfere with coaptation, or may have other material properties that are different from those of the primary leaflet material. As shown in FIG. **8**A, the reinforcement has a shape that conforms to the edge contour of the belly **862** of the leaflet. However, in other examples, the specific shape of the reinforcement **870** may be adjusted to provide reinforcement in any other regions of the leaflet **860**. The reinforcement **870** may comprise a material such as fabric, tissue, or one or more polymers.

The leaflet **860'** shown in FIG. **8**B is similar to the leaflet **860**, except that the reinforcement **870'** is wider at two corner locations **872** at which the belly **862** meets the free edge **868**. The corner locations **872** are the locations of the leaflet **860'** that are stitched to the commissure attachment features **44** of the stent **12** of the prosthetic heart valve **10**, so the leaflet **860'** may provide additional strength and suture retention support at these high-stress locations.

The leaflet **860"** shown in FIG. **8**C is also similar to the leaflet **860**, except that the reinforcement **870"** extends beyond the edge of the belly **862**. The inner edge **874** of the reinforcement **870"** overlaps with the primary leaflet material for the part of the reinforcement **870"** that is radially inside of the edge of the belly **862**. The outer edge **876** of the reinforcement **870"** extends beyond the edge of the belly **862**, such that there is no overlap with the primary leaflet material for the part of the reinforcement **870"** that is radially outside of the edge of the belly. In this variation, only the reinforcement **870"** and not the primary leaflet material is directly stitched to the stent **12** and/or the cuff **50**, so that the reinforcement **870"** bears a higher portion of the stress at the attachment points to the stent and/or the cuff. The reinforcement **870"** may be stronger than the primary leaflet material, so that permitting stress from the attachment of the leaflet **860"** to the stent **12** and/or the cuff **50** to be borne by the reinforcement may improve the durability of the primary leaflet material.

For any of the leaflets **860**, **860'**, and **860"**, various methods may be used to attach the reinforcement **870**, **870'**, or **870"** to the primary leaflet material. In one example, a single reinforcement **870**, **870'**, or **870"** may be sewn, glued, heat sealed or otherwise attached to a single surface of the primary leaflet material at or adjacent to the edge of the belly **862**. In another example, two separate reinforcements **870**, **870'**, or **870"** may be sewn, glued, heat sealed or otherwise attached to both the top and bottom surfaces of the primary leaflet material at or adjacent to the edge of the belly **862**. In yet another example, a single reinforcement **870**, **870'**, or **870"** may be sewn, glued, heat sealed or otherwise attached between two adjacent layers of primary leaflet material at or adjacent to the edge of the belly **862**.

The leaflet **960** shown in FIGS. **9**A and **9**B is a variant that is similar to the leaflet **860**, except that the leaflet **960** has two reinforcements **970***a*, **970***b* that extend from a central part of the belly **962** to opposite ends of the free edge **968**, with the width of each reinforcement narrowing in a direction from the free edge towards the central part of the belly. The reinforcements **970***a*, **970***b* each may comprise a material such as fabric, tissue, or one or more polymers. The reinforcements **970***a*, **970***b* may include a material having properties that are different from those of the primary leaflet material, such as a higher durometer than a durometer of the primary leaflet material, but not so high as to interfere with coaptation.

As can be seen in FIG. **9**B, the reinforcement **970***a* is attached to both opposite surfaces of the primary leaflet material. A single reinforcement **970***a* and a single reinforcement **970***b* may each wrap around a portion of the edge of the belly **962** of the leaflet **960**, or two separate reinforcements **970***a* and two separate reinforcements **970***b* may be attached on respective top and bottom surfaces **980**, **981** of

the primary leaflet material at or adjacent respective portions of the belly **962**. Any of the attachment techniques discussed above may be used, including adhesive, heat sealing or lamination, ultrasonic welding or suturing, as well as any other known technique.

FIGS. **10**A-**10**C illustrate a leaflet **1060** according to an embodiment of the invention that may replace each of the leaflets **60** described above with reference to the prosthetic heart valve **10**. The leaflet **1060** may be similar to the leaflet **60**, except that the leaflet **1060** has first, second, third, and fourth regions **1061**, **1063**, **1065**, and **1067** that have increasingly smaller respective thicknesses T**1**, T**2**, T**3**, and T**4**, as the distance from the edge of the belly **1062** increases. The difference between the greatest thickness T**1** and the smallest thickness T**4** is greater than 0.0015", which is not possible through normal variation of pericardium tissue thickness, which is typically used for tissue leaflets of prosthetic valves.

The leaflet **1060** is thickest in the first region **1061** at the belly **1062**, which is the area of attachment to the stent **12** and/or the cuff **50**, and the leaflet gets progressively thinner moving away from the belly and towards the center of the free edge **1068**. As shown in FIGS. **10**A-**10**C, the cross-section of the leaflet **1060** has a thickness that steps down at the transition between each successive region **1061-1067**.

The inventors have found that FEA analysis suggests that the highest stresses on conventional leaflets occurs near the belly of the leaflets, where the leaflet is attached to the stent and/or cuff. Altering the thickness of the leaflet **1060** such that it is thicker in the area of highest stresses near the belly **1062** may permit the leaflet to better withstand stresses in that portion of the leaflet compared to conventional leaflet designs.

If the entire leaflet **1060** was to have a sufficient thickness to more easily accommodate or withstand the stresses near the belly **1062**, then it may not be possible to sufficiently compress the prosthetic heart valve having the leaflets **1060** into a conventional delivery device for transfemoral delivery to a native annulus in a patient. Reducing the thickness of the leaflet **1060** from the belly **1062** towards the center of the free edge **1068** compared to a conventional tissue leaflet may provide a durability advantage for the leaflet at locations at which the stress is greatest, while reducing the collapsed volume of the leaflet by removing volume from areas of the leaflet where the stress is lower.

One exemplary method of forming the leaflet **1060** having regions **1061-1067** with thicknesses T**1**-T**4** is to mechanically remove tissue material using a shaver, blade or laser to create the different thicknesses. In the example shown in FIG. **10**C, a shaver **1066** having a small circular shaver head may be used to sculpt leaflet tissue having an initial thickness of at least T**1**, shaving away different amounts of material in different regions, so that the regions **1061-1067** will have the desired thicknesses T**1**-T**4**.

In another example, a chemical etching process may be used to reduce the thickness of each of the regions **1061-1067** to create the different thicknesses T**1**-T**4**. A mold may be placed over the initial leaflet tissue such that a chemical (e.g., acid or collagenase enzyme) could be selectively applied to each of the regions **1061-1067**. The amount of tissue removed could be controlled by the length of time the tissue is exposed to the chemical or the concentration of the chemical, with the highest time of exposure or the highest concentration of etching chemical being in region **1067** where the greatest thickness reduction is needed.

FIG. **10**D illustrates a leaflet **1060'** according to a variant that is similar to the leaflet **1060**, except that the leaflet **1060'** has a continuously varying thickness starting at T**1** near the belly **1062** and decreasing to T**4** as the distance from the edge of the belly increases to a maximum, which is at a center of the free edge **1068**.

FIG. **10**E illustrates a process that may be used to reduce the thickness of portions of the leaflet **1060'** in a continuously varying manner. An initial tissue leaflet may be placed on an angled plate **1080**, and a flat blade or a laser may be used to produce a straight cut line **1081** that is substantially parallel to a bottom surface **1082** of the angled plate but that is at an angle **1083** to a top surface **1084** of the angled plate.

As can be seen in FIG. **10**F, the angled plate **1080** would have a varied thickness in two dimensions, so that the resulting thickness of the leaflet **1060'** would vary somewhat similarly to the thickness of the leaflet **1060**, but in a continuously variable manner rather than in a stepwise manner. The straight cut line **1081** would remove more material near the center of the free edge **1068** than near the belly **1062**. The resulting thickness would be T**1** near the belly **1062** and T**4** at a center of the free edge.

FIG. **11**A illustrates a leaflet **1160** according to a variant that is similar to the leaflet **1060**, except that the leaflet **1160** is formed through an additive process to produce first, second, and third regions **1161-1163** with thicknesses T**1**-T**3**, rather than the subtractive processes described with reference to FIGS. **10**C and **10**E.

As shown in FIG. **11**B, formation of the leaflet **1160** may begin with thin tissue layers **1181**, **1182**, and **1183** of different surface areas but all with the same thickness T**3**, and the thin tissue layers may be vertically stacked so that the thinnest region **1163** has the thickness T**3** of a single layer **1183**, the middle region **1162** has a combined thickness T**2** of two stacked layers **1182** and **1183**, and the thickest region **1161** has a combined thickness T**1** of three stacked layers **1181-1183**.

The layers **1181-1183** could be stitched together with sutures **1184** as shown in FIG. **11**A, or alternatively, the tissue could be glued together with a fibrin glue, or stacked together and incubated with growth medium such that the cells present in the pericardium create collagen fibers to fuse the tissue together. If the cells already present in the pericardium are not sufficient to fuse the tissue, external cells such as fibroblasts could be seeded onto the tissue surfaces to be fused prior to incubation.

FIG. **11**C illustrates a leaflet **1160'** according to a variant that is similar to the leaflet **1160**, except that the leaflet **1160'** is formed through an additive process to produce first, second, and third regions **1161'-1163'** with thicknesses T**1**-T**3** by using tissue layers **1181'-1183'** having different thicknesses, rather than the same thickness.

As shown in FIG. **11**D, formation of the leaflet **1160'** may begin with initial tissue layers **1181'-1183'** of different surface areas and different thicknesses T**1**-T**3**, and the tissue layers may be laterally joined so that the final regions **1161'-1163'** have the same thicknesses as the respective initial tissue layers **1181'-1183'**. The layers **1181'-1183'** could be stitched together with sutures **1184** as shown in FIG. **11**C, or alternatively, the tissue could be glued together with a fibrin glue, or fused together as described above with reference to FIG. **11**B. In this variant, the layers **1181'-1183'** nest in one another, such that the convex outer contour of the layer **1182'** nests into the concave inner contour of the layer **1181'**, and the convex outer contour of the layer **1183'** nests into the concave inner contour of the layer **1182'**.

FIG. **12** illustrates leaflets **1260** according to an embodiment of the invention that may replace the leaflets **60** described above with reference to the prosthetic heart valve

10. The leaflet **1260** may be similar to the leaflet **60**, except that the leaflets **1260** are coupled together via the sutures **1274** and/or the sutures **1276**. The sutures **1274** and/or the sutures **1276** couple adjacent ones of the leaflets together such that when one starts to move, the other one also moves. Such coupling of the leaflets **1260** to one another may structurally reinforce the sutured region of the leaflets and may improve the balance of coaptation (i.e., all three leaflets coapting at the same time).

The sutures **1274** are disposed at the free edges **1268** of adjacent ones of the leaflets **1260** at the ends of the free edges adjacent the attachment to the commissure attachment features **44**. The sutures **1276** extend in an arc from the free edges **1268** of adjacent ones of the leaflets to the bellies **1262** of adjacent ones of the leaflets. Either one or both of the sutures **1274** and the sutures **1276** may be implemented in a single prosthetic heart valve, depending on the degree of coupling between the leaflets **1260** that is desired. Although sutures **1274** and **1276** are shown in FIG. **12**, in other examples, alternative mechanisms may be used to couple the leaflets **1260** to one another, such as a clip or staples made of a metal or a polymer.

The incorporation of any of the reinforcements described above may enable the prosthetic heart valve to provide visualization advantages during the deployment of the heart valve within a patient. During deployment, radiologic imaging, such as fluoroscopy, is often used to visualize the prosthetic heart valve and assure its proper positioning in the native valve annulus. Accurate positioning of the prosthetic heart valve is important in ensuring the prosthetic device functions properly. However, since many of the materials from which the prosthetic valves are formed are not radiopaque, such imaging is of limited help in accurately positioning the heart valve at the proper depth and rotational orientation in the native valve annulus.

In any of the embodiments described above, the internal skeleton or other reinforcement may be formed from a biocompatible material that is highly radiopaque, such as gold, tantalum, platinum, iridium, barium, tungsten, or any combination thereof, or any other biocompatible materials used for their radiographic properties in medical devices. For example, internal skeletons **170**, **170'**, **370** and **470** (including ribs **172**, **172'**, **372**, **372***c*, **372***d*, **372***e* and **472**), and reinforcement **570** may be formed from a highly radiopaque material. In addition, the sutures forming reinforcements **770** and **770'** may be formed from a highly radiopaque material. The radiopacity of these materials is significantly greater than the radiopacity of the primary leaflet material such that, when visualized under radiographic imaging, these reinforcing structures will be readily visible, identifying the rotational positions of the leaflets relative to the native valve structures, such as the native leaflet commissures. As such, it will be possible to rotate the prosthetic valve relative to the native valve structures to ensure the prosthetic valve is in the optimum position prior to its full deployment.

It will be appreciated that some of the reinforcements described above may be formed of fabric, tissue or polymers that are not inherently highly radiopaque. Although it may be possible to replace those materials with materials that are radiopaque, or to incorporate a radiopaque material in the fabric, tissue or polymer, or in regions thereof, as desired, that may not be always possible. At other times, each of the valve leaflets may have the same radiopaque internal skeleton or other reinforcing structure, such that the leaflets will be visible under radiographic imaging, but it will not be possible to discern one leaflet from another. In both of these situations, it may be possible to incorporate one or more radiopaque markers in all of the leaflets of the prosthetic valve, or less than all of the leaflets, as desired. Any such markers may be formed from the same materials as noted above, and may be formed in any geometric shape, including round, oval, rectangular, triangular, trapezoidal and the like, as well as in non-geometric shapes, including numbers, letters, arrows, or any other useful shape. All of the leaflets of a single prosthetic valve may have markers with the same shape and positions, or one or more leaflets may have markers with a shape and/or position that is different from those of the other leaflets. Additionally, where a leaflet has more than one marker, all of the markers on the leaflet may have the same shape or some or all of the markers on a leaflet may have different shapes.

The markers may be placed at those positions on the prosthetic heart valve leaflets it is desirable to identify or visualize during deployment of the prosthetic heart valve in a patient or possibly after the heart valve has been functioning in the patient for a period of time. For example, markers may be placed on the leaflets at positions at or adjacent the leaflet commissures to facilitate the accurate rotational orientation and positioning of the prosthetic heart valve relative to the native valve commissures and leaflets. As another example, markers may be placed at one or more locations along the free edge of each leaflet. When viewed under radiographic imaging, these markers may make it possible to visualize whether the leaflets are opening, closing and coapting properly during operation of the prosthetic heart valve. These markers may also make it possible to more readily discern using radiographic imaging that the prosthetic heart valve continues to operate properly after a period of time following implantation in a patient.

Although the invention herein has been described with reference to collapsible and/or expandable prosthetic heart valve embodiments, it is to be understood that the stress-reducing leaflet features described herein (e.g., the internal skeletons and the reinforcements) may also be applied to leaflets of mechanical heart valves. Exemplary mechanical heart valves to which the features described herein may be applied are described in the U.S. provisional patent application 62/902,044, the disclosure of which is hereby incorporated by reference herein.

In summary, the disclosure herein describes multiple embodiments of a prosthetic heart valve including an expandable stent having an inflow end, an outflow end, an annulus section adjacent the inflow end, and a plurality of cells connected to one another in a plurality of annular rows around the stent; a cuff attached to the annulus section of the stent; a plurality of leaflets disposed within an interior region of the stent and attached to at least one of the cuff or the stent, the leaflets together having a coapted position occluding the interior region of the stent and an open position in which the interior region is not occluded, each of the leaflets including a primary leaflet material; and a reinforcement attached to the primary leaflet material of each of the leaflets, the reinforcement including a material having properties that are different from properties of the primary leaflet material; and/or

the reinforcement may include a plurality of ribs that are spaced apart from one another in a direction that is parallel to an outer surface of a respective one of the leaflets; and/or

each of the ribs may be disposed in an interior volume of the leaflet and may include an extension that extends out from the interior volume of the leaflet, and the extensions may be coupled to commissure attachment features of the stent; and/or

each of the ribs may be formed from the primary leaflet material; and/or

the reinforcement may include a single curved rib having a shape that matches a contour of a belly of a respective one of the leaflets; and/or

the reinforcement may include a single rib that extends along a free edge of a respective one of the leaflets; and/or

the reinforcement may extend between two leaflet layers that overlie one another on opposite sides of the reinforcement, the two leaflet layers being fixed to one another; and/or

the primary leaflet material may have a first radiopacity and the reinforcement may be formed from a material having a second radiopacity greater than the first radiopacity; and/or

the reinforcement may be attached to an outer surface of the primary leaflet material of each of the leaflets; and/or

the reinforcement may include a single strip-shaped sheet of material that extends along a free edge of the leaflet; and/or

the reinforcement may include a sheet of fabric extending from a portion of a belly of the leaflet towards a central region of the leaflet; and/or

each of the leaflets may include a belly having a curved edge, and the reinforcement may include a curved strip of material extending along the curved edge of the belly and having a shape that matches the curved edge of the belly; and/or

the curved strip of material may include a first portion that overlies the curved edge of the belly and a second portion that extends outwardly beyond the curved edge of the belly, the second portion of the curved strip of material being directly attached to the stent or the cuff; and/or

the reinforcement may include two spaced-apart strips of material each extending along a respective portion of the curved edge of a belly; and/or

the reinforcement may include a material having a higher durometer than a durometer of the primary leaflet material.

Also described herein are multiple embodiments of a prosthetic heart valve including an expandable stent having an inflow end, an outflow end, an annulus section adjacent the inflow end, and a plurality of cells connected to one another in a plurality of annular rows around the stent; a cuff attached to the annulus section of the stent; a plurality of leaflets disposed within an interior region of the stent and attached to at least one of the cuff or the stent, the leaflets together having a coapted position occluding the interior region of the stent and an open position in which the interior region is not occluded, each of the leaflets including as primary leaflet material; and a reinforcement attached to the primary leaflet material of each of the leaflets, the reinforcement including a series of sutures exposed in a central region of an outer surface of the leaflet.

Further described herein are multiple embodiments of a prosthetic heart valve including an expandable stent having an inflow end, an outflow end, an annulus section adjacent the inflow end, and a plurality of cells connected to one another in a plurality of annular rows around the stent; a cuff attached to the annulus section of the stent; a plurality of leaflets disposed within an interior region of the stent and attached to at least one of the cuff or the stent, the leaflets together having a coapted position occluding the interior region of the stent and an open position in which the interior region is not occluded, each of the leaflets including a primary leaflet material, and each of the leaflets having a thickness that varies from a belly edge of the leaflet to a free edge of the leaflet; and/or

each of the leaflets may have an outer surface and a plurality of regions adjacent to one another in lateral directions parallel to the outer surface, a first one of the regions adjacent the belly edge having a first constant thickness and a second one of the regions adjacent the free edge having a second constant thickness less than the first constant thickness; and/or

the first one of the regions may be formed from first and second layers of the primary leaflet material, the first layer may be stacked atop the second layer so that the first and second layers together have the first constant thickness, and the second one of the regions may be formed from the second layer that has the second constant thickness; and/or

the first one of the regions may be formed from a first layer of the primary leaflet material that has the first constant thickness, and the second one of the regions may be formed from a second layer of the primary leaflet material that has the second constant thickness, and the first and second layers may be disposed adjacent to one another in the lateral directions; and/or

the thickness of each of the leaflets may smoothly transition from a first thickness at the belly edge of the leaflet to a second thickness at a center of the free edge of the leaflet, the first thickness being greater than the second thickness; and/or

the primary leaflet material may have a first radiopacity and at least one of the leaflets may include a marker having a second radiopacity greater than the first radiopacity.

Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present invention as defined by the appended claims.

It will be appreciated that the various dependent claims and the features set forth therein can be combined in different ways than presented in the initial claims. It will also be appreciated that the features described in connection with individual embodiments may be shared with others of the described embodiments.

The invention claimed is:

1. A prosthetic heart valve, comprising:

an expandable stent having an inflow end, an outflow end, an annulus section adjacent to the inflow end, and a plurality of cells connected to one another in a plurality of annular rows around the stent;

a cuff attached to the annulus section of the stent;

a plurality of leaflets disposed within an interior region of the stent and attached to at least one of the cuff or the stent, the leaflets together having a coapted position occluding the interior region of the stent and an open position in which the interior region is not occluded, each of the leaflets including a primary leaflet material; and

a reinforcement attached to the primary leaflet material of each of the leaflets, the reinforcement including a material having properties that are different from properties of the primary leaflet material;

wherein the reinforcement includes a plurality of ribs that are spaced apart from one another in a direction that is parallel to an outer surface of a respective one of the leaflets; and

wherein each of the plurality of ribs includes an extension that extends out from the leaflet, the extensions being coupled to commissure attachment features of the stent.

2. The prosthetic heart valve of claim **1**, wherein the plurality of ribs are disposed in an interior volume of the leaflet.

3. The prosthetic heart valve of claim **1**, wherein the reinforcement extends between two leaflet layers that overlie one another on opposite sides of the reinforcement, the two leaflet layers being fixed to one another.

4. The prosthetic heart valve of claim **1**, wherein the primary leaflet material has a first radiopacity and the reinforcement is formed from a material having a second radiopacity greater than the first radiopacity.

5. The prosthetic heart valve of claim **1**, wherein the reinforcement is attached to an outer surface of the primary leaflet material of each of the leaflets.

6. The prosthetic heart valve as claimed in claim **1**, wherein the reinforcement includes a material having a higher durometer than a durometer of the primary leaflet material.

7. The prosthetic heart valve of claim **1**, wherein the plurality of ribs are partially embedded within an interior volume of the leaflet.

8. The prosthetic heart valve of claim **1**, wherein the plurality of ribs are woven between fibers of the primary leaflet material.

9. The prosthetic heart valve of claim **1**, wherein the plurality of ribs have a roughened outer surface.

10. The prosthetic heart valve of claim **1**, wherein the plurality of ribs are spaced out between a free edge of the leaflet and a belly of the leaflet.

11. The prosthetic heart valve of claim **1**, wherein the plurality of ribs are bowed to a radius of curvature between that of a free edge of the respective leaflet and a belly of the leaflet.

12. A prosthetic heart valve, comprising:

an expandable stent having an inflow end, an outflow end, an annulus section adjacent the inflow end, and a plurality of cells connected to one another in a plurality of annular rows around the stent;

a cuff attached to the annulus section of the stent; and

a plurality of leaflets disposed within an interior region of the stent and attached to at least one of the cuff or the stent, the leaflets together having a coapted position occluding the interior region of the stent and an open position in which the interior region is not occluded, each of the leaflets including a primary leaflet material, and each of the leaflets having a thickness that varies from a belly edge of the leaflet to a free edge of the leaflet;

wherein each of the leaflets has an outer surface and a plurality of regions adjacent to one another in lateral directions parallel to the outer surface, a first one of the regions adjacent the belly edge having a first constant thickness and a second one of the regions adjacent the free edge having a second constant thickness less than the first constant thickness;

wherein the first one of the regions is formed from first and second layers of the primary leaflet material, the first layer is stacked atop the second layer so that the first and second layers together have the first constant thickness, and the second one of the regions is formed from the second layer that has the second constant thickness.

13. The prosthetic heart valve of claim **12**, wherein the primary leaflet material has a first radiopacity and at least one of the leaflets includes a marker having a second radiopacity greater than the first radiopacity.

14. The prosthetic heart valve of claim **12**, wherein the primary leaflet material has a first radiopacity and at least one of the leaflets includes a marker having a second radiopacity greater than the first radiopacity.

15. A prosthetic heart valve, comprising:

an expandable stent having an inflow end, an outflow end, an annulus section adjacent the inflow end, and a plurality of cells connected to one another in a plurality of annular rows around the stent;

a cuff attached to the annulus section of the stent; and

a plurality of leaflets disposed within an interior region of the stent and attached to at least one of the cuff or the stent, the leaflets together having a coapted position occluding the interior region of the stent and an open position in which the interior region is not occluded, each of the leaflets including a primary leaflet material, and each of the leaflets having a thickness that varies from a belly edge of the leaflet to a free edge of the leaflet;

wherein each of the leaflets has an outer surface and a plurality of regions adjacent to one another in lateral directions parallel to the outer surface, a first one of the regions adjacent the belly edge having a first constant thickness and a second one of the regions adjacent the free edge having a second constant thickness less than the first constant thickness;

wherein the first one of the regions is formed from a first layer of the primary leaflet material that has the first constant thickness, and the second one of the regions is formed from a second layer of the primary leaflet material that has the second constant thickness, and the first and second layers are disposed adjacent to one another in the lateral directions.

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